Food and Drug Regulation:

STATUTORY AND REGULATORY SUPPLEMENT

2024 EDITION

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PREFACE

This Statutory and Regulatory Supplement ("Supplement") is intended for use with its companion casebook, *Food and Drug Regulation: A Statutory Approach* (2021). For an overview of the way this Supplement is intended to work with the casebook, see pages 3-8 of the casebook.

This is not a traditional statutory supplement. Instead, it contains selected, aggressively edited provisions of the Federal Food, Drug and Cosmetic Act (FFDCA), related statutes, and the Code of Federal Regulations.[1] The Supplement includes all provisions assigned as reading in the casebook, as well as selected additional provisions that some professors may wish to cover. The excerpts are designed to be teachable rather than comprehensive.

The Two Forms of the FFDCA

The FFDCA is generally available to lawyers in two forms. The first is the original statute, as amended. This is the formal legal text derived from the U.S. session laws, with section numbers and language that matches the laws as actually passed by Congress. It is not freely available online as a compiled document and is not available as a compiled document on major commercial databases. However, unofficial versions are available for purchase in both print and electronic format.[2]

The second is the FFDCA as incorporated into Title 21 of the United States Code (U.S. Code).[3] This is the statute as edited by the Office of Law Revision Counsel (OLRC) of the U.S. House of Representatives. The form in the U.S. Code is not the formal text of the FFDCA. It contains editorial enhancements (including some useful subsection headings) and its section numbers are

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[1] Steps taken to abridge the material include: omission of numerous sections of the various statutes and regulations; omission of large amounts of text of individual sections; omission of exceptions, clarifications, and specifications when they break up the flow of a core sentence; omission of past dates by which FDA was required to take some actions; omission of definitions of states and territories; omission of petition, review, and appeal provisions specific to some particular sections; omission of public and private consultation requirements; omission of explicit statutory references to common terms ("drug, as defined in § 201(g)"); omission of authorizations for appropriations; and omission of various special rules for small manufacturers. Within statutory and regulatory sections, omitted information is indicated with ellipses or bracketed explanations. As this supplement is not intended to be comprehensive, no indication is made when a full section of a statute or regulation is omitted. To highlight the structure of the statute, and to make it more readable, line breaks and indentations have been added to numbered (or lettered) lists throughout this supplement.

[2] Recent versions are available from the Food and Drug Law Institute, EMILY K. STRUNK ET AL, FDCA STATUTORY SUPPLEMENT (2d ed. 2021), and West Academic, PETER BARTON HUTT & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: STATUTORY SUPPLEMENT (2023 ed.).

[3] For an overview of the relationship between codified text and other statutory compilations, see Jarrod Shobe, *Codification and the Hidden Work of Congress*, 67 U.C.L.A. L. REV. 640, 640-660 (2020).

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different from the section numbers in the original statute, as amended. The form of the FFDCA included in the U.S. Code is also the form easily available online. It can be accessed freely on the OLRC website and is included—in both annotated and unannotated format—in major commercial databases such as Lexis and Westlaw.

Broadly speaking, food and drug specialists tend to rely on the original statute, as amended. Lawyers who are not food and drug specialists tend to rely on the form of the statute that appears in the U.S. Code. However, neither existing form is ideal for use in a law-school course.

The original statute, as amended, has memorable section numbers but lacks many of the subsection headings of the codified form. The codified form has more subsection headings but uses section numbers that are far more difficult to remember. And both contain many sections that are too long and detailed to assign as student reading. To address these disadvantages, this supplement combines the best features of the original statute and the codified form.

The Approach of this Supplement

This Supplement merges the two existing forms of the statute. This results in a shorter, abridged version designed for use in an upper-division law-school course. It uses the section numbers of the original statute, as amended (including for cross-references) and the subheadings of the U.S. Code.[4]

For all other statutes, the excerpted language is taken solely from the U.S. Code. Excerpts from the Code of Federal Regulation are taken from the Electronic Code of Federal Regulations.[5]

The Charts

This Supplement also includes seven detailed charts. These are listed on the following page.

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[4] To match the text of the original statute, as amended, stock phrases added as part of the codification process (such as "of this title" following a cross-reference to another FFDCA section), have been omitted. Similarly, references to "this chapter" in the U.S. Code version have been returned to the statutory language, "this Act."

[5] The Electronic Code of Federal Regulations is currently available at https://www.ecfr.gov/. It is not the official legal text of the Code of Federal Regulations. However, it is published jointly by two federal agencies (the Government Publishing Office and the National Archives and Records Administration's Office of the Federal Register) and updated daily.

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Chart 1	The 54 Titles of the U.S. Code	p. 25
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Chart 7	C.F.R. "Sections" Excerpted in this Supplement	p. 79

As you begin to consolidate your knowledge of the course material, you may find Charts 3, 6, and 7 to be particularly helpful. Chart 3 is a list of all provisions of the FFDCA. It contains many details that will help you put the statute in historical context.[6] Chart 6 lists all Parts of C.F.R. Title 21 and can give you a useful overview of the regulatory structure. Chart 7 lists all C.F.R. sections excerpted in this supplement, as well as the date of the most recent amendment to each.

The remaining four charts are intended primarily to provide context for the included excerpts. Charts 1 and 2 provide context for the FFDCA, while charts 4 and 5 provide context for C.F.R. Title 21.

The Chapter Guides

This Supplement includes, as an Appendix, a set of Chapter Guides for the casebook. Each Chapter Guide lists the Supplement readings assigned within that chapter of the casebook. It includes both the casebook page on which each reading is assigned and the Supplement page on which each reading can be found. The Appendix begins on page 495 of this Supplement.

The 2024 Edition

Material in this Supplement is current as of May 15, 2024. This 2024 Edition incorporates changes to the FFDCA and other excerpted material since May 15, 2023 (the cutoff date for the 2023 Edition). This includes the Continuing Appropriations Act, 2024 and Other Extensions Act,

[6] This chart includes, for every provision: the FFDCA section number; the U.S.C. section number; core information on the session law enacting that provision; core information on the most recent session law amending that provision; and information on whether that provision is excerpted in this supplement.

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enacted on September 30, 2023.[7] This 2024 Edition also incorporates the entry into force of several time-delayed provisions of the Modernization of Cosmetics Regulation Act (MoCRA),[8] a small change to the Administrative Procedure Act made by the Providing Accountability Through Transparency Act of 2023,[9] several corrections to the excerpted statutory language, and various updates to the excerpted regulations.

[7] Pub. L. No. 118-15, 137 Stat. 71 (2023). This statute altered user-fee provisions not excerpted in this Supplement. However, the the changed user-fee provisions are noted in Chart 3.

[8] Pub. L. No. 117-328, 136 Stat. 4459, 5847-5860 (2022).

[9] Pub. L. No. 118-9, 137 Stat. 55 (2023).

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CHARTS

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Chart 1: The 54 Titles of the U.S. Code

The 54 Titles of the United States Code		
Title 1. General Provisions	Title 19. Customs Duties	Title 37. Pay or Allowances of the Uniformed Services
Title 2. The Congress	Title 20. Education	Title 38. Veterans Benefits
Title 3. The President	**Title 21. Food and Drug**	Title 39. Postal Service
Title 4. Flag and Seal, Seat of Government, and the States	Title 22. Foreign Relations and Intercourse	Title 40. Public Buildings, Properties, and Works
Title 5. Government Organization and Employees	Title 23. Highways	Title 41. Public Contracts
Title 6. Domestic Security	Title 24. Hospitals and Asylums	Title 42. The Public Health and Welfare
Title 7. Agriculture	Title 25. Indians	Title 43. Public Lands
Title 8. Aliens and Nationality	Title 26. Internal Revenue Code	Title 44. Public Printing and Documents
Title 9. Arbitration	Title 27. Intoxicating Liquors	Title 45. Railroads
Title 10. Armed Forces	Title 28. Judiciary and Judicial Procedure	Title 46. Shipping
Title 11. Bankruptcy	Title 29. Labor	Title 47. Telecommunications
Title 12. Banks and Banking	Title 30. Mineral Lands and Mining	Title 48. Territories and Insular Possessions
Title 13. Census	Title 31. Money and Finance	Title 49. Transportation
Title 14. Coast Guard	Title 32. National Guard	Title 50. War and National Defense
Title 15. Commerce and Trade	Title 33. Navigation and Navigable Waters	Title 51. National and Commercial Space Programs
Title 16. Conservation	Title 34. Crime Control and Law Enforcement	Title 52. Voting and Elections
Title 17. Copyrights	Title 35. Patents	Title 53. [Reserved]
Title 18. Crimes and Criminal Procedure	Title 36. Patriotic and National Observances, Ceremonies, and Organizations	Title 54. National Park Service and Related Programs

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Chart 2: The Structure of U.S. Code Title 21—Food and Drugs

Structure of U.S. Code Title 21		
Chapter #	*Chapter Name*	*Sections*
1	Adulterated or misbranded foods or drugs	1-26
2	Teas	41-50
3	Filled milk	61-64
4	Animals, meats, and meat and dairy products	71-149
5	Viruses, serums, toxins, antitoxins, and analogous products	151-159
5A	Bureau of narcotics	161-165
6	Narcotic drugs	171-200b
7	Practice of pharmacy and sale of poisons in consular districts in China	201-215
8	Narcotic farms	221-237
9	**Federal food, drug, and cosmetic act**	**321-399i**
10	Poultry and poultry products inspection	451-473
11	Manufacture of narcotic drugs	501-517
12	Meat inspection	601-695
13	Drug abuse prevention and control	801-971
14	Alcohol and drug abuse educational programs and activities	1001-1007
15	Egg products inspection	1031-1056
16	Drug abuse prevention, treatment, and rehabilitation	1101-1194
17	National drug enforcement policy	1201-1204
18	President's media commission on alcohol and drug abuse prevention	1301-1308
19	Pesticide monitoring improvements	1401-1403
20	National drug control program	1501-1536
21	Biomaterials access assurance	1601-1606
22	National drug control policy	1701-1715
23	National youth anti-drug media campaign	1801-1804
24	International narcotics trafficking	1901-1908
25	Miscellaneous anti-drug abuse provisions	2001-2014
26	Food safety	2101-2110
27	Food safety modernization	2201-2252
28	Sanctions with respect to foreign traffickers of illicit synthetic opioids	2301-2335
29	International sports doping	2401-2404

Note that some of the chapters listed above remain in the U.S. Code (essentially as placeholders) even though much or all of their content has been repealed or has been editorially omitted from the code. For

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example, Title 21, Chapter 1, Subchapter I was the former location of the Federal Food and Drugs Act (1906). That statute was repealed by the statute that is the focus of this supplement, the Federal Food, Drug, and Cosmetics Act of 1938. Some other content, however, remains in Title 21, Chapter 1, Subchapter II.

With respect to editorial omissions, the government entity responsible for maintaining the U.S. Code, the Office of Law Revision Counsel of the U.S. House of Representatives, explains editorial omissions as follows:

> "Omitted" is used to indicate that statutory text has been deleted for a reason other than that it was repealed. When "omitted" is used in a section catchline, it indicates that the section has been deleted because it was amended out of existence or because it is obsolete, terminated, or expired. When "omitted" is used for a unit of a section or of a statutory note, it indicates that the unit has been deleted because it amended another provision or because it is obsolete, terminated, or expired. Information about omitted material in a section can usually be found in a Codification note under that section.

U.S. House of Representatives, Office of Law Revision Counsel, Frequently Asked Questions, https://uscode.house.gov/faq.xhtml (last visited June 15, 2021). For example, Title 21, Chapter 5A, has been editorially omitted from the U.S. Code. That chapter established an office that was made obsolete by government reorganizations in the 1960s and 1970s. Among other things, those reorganizations transferred the relevant functions from the Department of the Treasury to the Department of Justice. *See generally* Title 21, Chapter 5A, Editorial Notes.

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Chart 3: The Federal Food, Drug, and Cosmetic Act of 1938, As Amended

FFDCA §1–1013; 21 U.S.C. § 301–399d. The chart below includes all of Title 21, Chapter 9. Most of these are provisions of the FFDCA, but other statutory provisions codified in Title 21, Chapter 9 are also included. These are indicated by an "N/A" (Not Applicable) in the chart's first column, "FFDCA §." Transferred (i.e., renumbered), editorially omitted, and repealed sections are listed only where the relevant section number (FFDCA §, USC §, or both) has not yet been given new content. These are indicated by gray text.

FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
Chapter I (1)	**Subchapter I (301)**	**Short Title**			
1	301	Short title	PL 75-717, 52 Stat. 1040, 1040 (1938-06-25)	Not amended	Y
Chapter II (201)	**Subchapter II (321–321d)**	**Definitions**			
201	321	Definitions; generally	PL 75-717, 52 Stat. 1040, 1040 (1938-06-25)	PL 117-328, 136 Stat. 5838 (2022-12-29)	Y
N/A	321a	"Butter" defined	PL 67-519, 42 Stat. 1500, 1500 (1923-03-04)	Not amended	N
N/A	321b	"Package" defined	PL 66-27 41 Stat. 271, 271 (1919-07-24)	Not amended	N
N/A	321c	Nonfat dry milk; "milk" defined	PL 78-244, 58 Stat. 108, 108 (1944-03-02)	PL 84-646, 70 Stat. 486, 486 (1956-07-02)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
N/A	321d	Market names for catfish and ginseng	PL 107-171, 116 Stat. 134, 526 (2002-05-13)	Not amended	N
Chapter III (301–311)	**Sub-chapter III (331–337a)**	**Prohibited Acts and Penalties**			
301	331	Prohibited acts	PL 75-717, 52 Stat. 1040, 1042 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5805, 5824, 5833, 5858 (2022-12-29)	Y
302	332	Injunction proceedings	PL 75-717, 52 Stat. 1040, 1043 (1938-06-25)	PL 103-80, 107 Stat. 773, 775 (1993-08-13)	Y
303	333	Penalties	PL 75-717, 52 Stat. 1040, 1043 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5805 (2022-12-29)	Y
N/A	333a	*Forfeiture and illegal trafficking in steroids*	PL 100-690, 102 Stat. 4181, 4230 (1988-11-18)	*Repealed by* PL 101-647, 104 Stat. 4789, 4853 (1990-11-29)	N
304	334	Seizure	PL 75-717, 52 Stat. 1040, 1044 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5805 (2022-12-29)	Y
305	335	Hearing before report of criminal violation	PL 75-717, 52 Stat. 1040, 1045 (1938-06-25)	Not amended	Y
306	335a	Debarment, temporary denial of approval and Suspension	PL 102-282, 106 Stat. 149, 150 (1992-05-13)	PL 115-271, 132 Stat. 3894, 3938 (2018-10-24)	Y
307	335b	Civil penalties	PL 102-282, 106 Stat. 149, 159 (1992-05-13)	PL 103-80, 107 Stat. 773, 776 (1993-08-13)	Y
308	335c	Authority to withdraw approval of abbreviated drug Applications	PL 102-282, 106 Stat. 149, 160 (1992-05-13)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
309	336	Report of minor violations	PL 75-717, 52 Stat. 1040, 1045 (1938-06-25)	PL 102-282, 106 Stat. 149, 150 (1992-05-13)	Y
310	337	Proceedings in name of United States; provision as to subpoenas	PL 75-717, 52 Stat. 1040, 1046 (1938-06-25)	PL 102-282, 106 Stat. 149, 150 (1992-05-13)	N
311	337a	Sec. 337a - Extraterritorial jurisdiction	PL 112-144, 126 Stat. 993, 1077 (2012-07-09)	Not amended	Y
Chapter IV (401–424)	**Subchapter IV (341–350m)**	**Food**			
401	341	Definitions and standards for food	PL 75-717, 52 Stat. 1040, 1046 (1938-06-25)	PL 103-80, 107 Stat. 773, 776 (1993-08-13)	Y
402	342	Adulterated food	PL 75-717, 52 Stat. 1040, 1046 (1938-06-25)	PL 109-59, 119 Stat. 1144, 1911 (2005-08-10)	Y
403	343	Misbranded food	PL 75-717, 52 Stat. 1040, 1047 (1938-06-25)	PL 111-148, 124 Stat. 119, 573 (2010-03-23)	Y
403A	343-1	National uniform nutrition labeling	PL 101-535, 104 Stat. 2353, 2362 (1990-11-08)	PL 111-148, 124 Stat. 119, 576 (2010-03-23)	N
403B	343-2	Dietary supplement labeling exemptions	PL 103-417, 108 Stat. 4325, 4328 (1994-10-25)	Not amended	Y
403C	343-3	Disclosure	PL 105-115, 111 Stat. 2296, 2353 (1997-11-21)	Not amended	N
N/A	343a	Health risks presented by use of saccharin	PL 95-203, 91 Stat. 1451, 1453 (1977-11-23)	Repealed PL 106-554, 114 Stat. 2763, 2763A-73 (2000-12-21)	N
404	344	Emergency permit control	PL 75-717, 52 Stat. 1040, 1048 (1938-06-25)	Not amended	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
405	345	Regulations making exemptions	PL 75-717, 52 Stat. 1040, 1049 (1938-06-25)	PL 101-535, 104 Stat. 2353, 2362 (1990-11-08)	N
406	346	Tolerances for poisonous or deleterious substances in food regulations	PL 75-717, 52 Stat. 1040, 1049 (1938-06-25)	PL 86-618, 74 Stat. 397, 398 (1960-07-12)	Y
408	346a	Tolerances and exemptions for pesticide chemical residue	PL 83-518, 68 Stat. 511, 511 (1954-07-22)	PL 117-328, 136 Stat. 4459, 6002 (2022-12-29)	Y
N/A	346b	Authorization of appropriations	PL 83-518, 68 Stat. 511, 517 (1954-07-22)	Not amended	N
407	347	Intrastate sales of colored oleomargarine	PL 81-459, 64 Stat. 20, 20 (1950-03-16)	Not amended	N
N/A	347a	Congressional declaration of policy regarding oleomargarine sales	PL 81-459, 64 Stat. 20, 20 (1950-03-16)	Not amended	N
N/A	347b	Contravention of state laws	PL 81-459, 64 Stat. 20, 22 (1950-03-16)	Not amended	N
409	348	Food additives	PL 85-929, 72 Stat. 1784, 1785 (1958-09-06)	PL 115-234, 132 Stat. 2427, 2440 (2018-08-14)	Y
410	349	Bottled drinking water standards; publication in Federal Register	PL 93-523, 88 Stat. 1660, 1694 (1974-12-16)	PL 104-182, 110 Stat. 1613, 1684 (1996-08-06)	N
411	350	Vitamins and minerals	PL 94-278, 90 Stat. 401, 410 (1976-04-22)	PL 103-417, 108 Stat. 4325, 4328, 4331 (1994-10-25)	Y
412	350a	Infant formulas	PL 96-359, 94 Stat. 1190, 1190 (1980-09-26)	PL 117-328, 136 Stat. 4459, 5838, 5840 (2022-12-29)	N
N/A	350a-1	Protecting infants and improving formula supply	PL 117-328, 136 Stat. 4459, 5838 (2022-12-29)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
413	350b	New dietary ingredients	PL 103-417, 108 Stat. 4325, 4331 (1994-10-25)	PL 111-353, 124 Stat. 3385, 3920 (2011-01-04)	Y
414	350c	Maintenance and inspection of records	PL 107-188, 116 Stat. 594, 669 (2002-06-12)	PL 111-353, 124 Stat. 3385, 3886 (2011-01-04)	N
415	350d	Registration of food facilities	PL 107-188, 116 Stat. 594, 667 (2002-06-12)	PL 111-353, 124 Stat. 3385, 3887, 3889 (2011-01-04)	Y
416	350e	Sanitary transportation practices	PL 109-59, 119 Stat. 1144, 1911 (2005-08-10)	Not amended	N
417	350f	Reportable food registry	PL 110-85, 121 Stat. 823, 965 (2007-09-27)	PL 111-353, 124 Stat. 3385, 3951 (2011-01-04)	N
418	350g	Hazard analysis and risk-based preventive controls	PL 111-353, 124 Stat. 3385, 3889 (2011-01-04)	Not amended	Y
419	350h	Standards for produce safety	PL 111-353, 124 Stat. 3385, 3899 (2011-01-04)	Not amended	N
420	350i	Protection against intentional adulteration	PL 111-353, 124 Stat. 3385, 3905 (2011-01-04)	Not amended	N
421	350j	Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry	PL 111-353, 124 Stat. 3385, 3923 (2011-01-04)	Not amended	N
422	350k	Laboratory accreditation for analyses of foods	PL 111-353, 124 Stat. 3385, 3926 (2011-01-04)	Not amended	N
423	350l	Mandatory recall authority	PL 111-353, 124 Stat. 3385, 3939 (2011-01-04)	Not amended	N
N/A	350l-1	Annual report to Congress	PL 111-353, 124 Stat. 3385, 3943 (2011-01-04)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
424	350m	Requirements for critical food	PL 117-328, 136 Stat. 4459, 5844 (2022-12-29)	Not amended	N
Chapter V (501–586H)	**Subchapter V (351–360fff-8)**	**Drugs and Devices**			
Subchapter A (501–524B)	*Part A (351–360n-2)*	*Drugs and Devices*			
501	351	Adulterated drugs and devices	PL 75-717, 52 Stat. 1040, 1049 (1938-06-25)	PL 115-52, 131 Stat. 1005, 1056 (2017-08-18)	Y
502	352	Misbranded drugs and devices	PL 75-717, 52 Stat. 1040, 1050 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5893 (2022-12-29)	Y
503	353	Exemptions and consideration for certain drugs, devices, and biological products	PL 75-717, 52 Stat. 1040, 1051 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5877 (2022-12-29)	Y
503A	353a	Pharmacy compounding	PL 105-115, 111 Stat. 2296, 2328 (1997-11-21)	PL 113-54, 127 Stat. 587, 598 (2013-11-27)	Y
503A-1	353a-1	Enhanced Communication	PL 113-54, 127 Stat. 587, 597 (2013-11-27)	Not amended	N
503B	353b	Outsourcing facilities	PL 113-54, 127 Stat. 587, 588 (2013-11-27)	Not amended	N
503C	353c	Prereview of television advertisements	PL 110-85, 121 Stat. 823, 939 (2007-09-27)	PL 113-54, 127 Stat. 587, 588 (2013-11-27)	N
503D	353d	Process to update labeling for certain generic drugs	PL 116-260, 134 Stat. 1182, 2933 (2020-12-27)	Not amended	N
504	354	Veterinary feed directive drugs	PL 104-250, 110 Stat. 3151, 3155 (1996-10-09)	PL 108-282, 118 Stat. 891, 903 (2004-08-02)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
505	355	New drugs	PL 75-717, 52 Stat. 1040, 1052 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5807, 5821, 5829, 5831, 5860 (2022-12-29)	Y
505-1	355-1	Risk evaluation and mitigation strategies	PL 110-85, 121 Stat. 823, 926 (2007-09-27)	PL 117-328, 136 Stat. 4459, 5829 (2022-12-29)	Y
N/A	355-2	Actions for delays of generic drugs and biosimilar biological products	PL 116-94, 133 Stat. 2534, 3130 (2019-12-20)	Not amended	N
505A	355a	Pediatric studies of drugs	PL 105-115, 111 Stat. 2296, 2305 (1997-11-21)	PL 117-9, 135 Stat. 256, 258 (2021-04-23)	N
N/A	355b	Adverse-event reporting	PL 107-109, 115 Stat. 1408, 1422 (2002-01-04)	PL 108-155, 117 Stat. 1936, 1942 (2003-12-03)	N
505B	355c	Research into pediatric uses for drugs and biological products	PL 108-155, 117 Stat. 1936, 1936 (2003-12-03)	PL 117-328, 136 Stat. 4459, 5806 (2022-12-29)	N
N/A	355c-1	Report	PL 112-144, 126 Stat. 993, 1045 (2012-07-09)	PL 115-52, 131 Stat. 1005, 1044 (2017-08-18)	N
505C	355d	Internal committee for review of pediatric plans, assessments, deferrals, and waivers	PL 110-85, 121 Stat. 823, 875 (2007-09-27)	PL 115-52, 131 Stat. 1005, 1047 (2017-08-18)	N
505D	355e	Pharmaceutical security	PL 110-85, 121 Stat. 823, 952 (2007-09-27)	Not amended	N
505E	355f	Extension of exclusivity period for new qualified infectious disease products	PL 112-144, 126 Stat. 993, 1077 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5826 (2022-12-29)	N
505F	355g	Utilizing real world evidence	PL 114-255, 130 Stat. 1033, 1096 (2016-12-13)	PL 115-52, 131 Stat. 1005, 1076 (2017-08-18)	N
505G	355h	Regulation of certain nonprescription drugs that are marketed without an approved drug application	PL 116-136, 134 Stat. 281, 435 (2020-03-27)	Not amended	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
506	356	Expedited approval of drugs for serious or life-threatening diseases or conditions	PL 105-115, 111 Stat. 2296, 2309 (1997-11-21)	PL 117-328, 136 Stat. 4459, 5822 (2022-12-29)	Y
N/A	356-1	Accelerated approval of priority countermeasures	PL 107-188, 116 Stat. 594, 613 (2002-06-12)	Not amended	N
506A	356a	Manufacturing changes	PL 105-115, 111 Stat. 2296, 2313 (1997-11-21)	Not amended	N
506B	356b	Reports of postmarketing studies	PL 105-115, 111 Stat. 2296, 2331 (1997-11-21)	PL 117-328, 136 Stat. 4459, 5823 (2022-12-29)	N
506C	356c	Discontinuance or interruption in the production of life-saving drugs	PL 105-115, 111 Stat. 2296, 2332 (1997-11-21)	PL 117-328, 136 Stat. 4459, 5806 (2022-12-29)	N
506C-1	356c-1	Annual reporting on drug shortages	PL 112-144, 126 Stat. 993, 1102 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5875 (2022-12-29)	N
506D	356d	Coordination; task force and strategic plan	PL 112-144, 126 Stat. 993, 1103 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5874 (2022-12-29)	N
506E	356e	Drug shortage list	PL 112-144, 126 Stat. 993, 1104 (2012-07-09)	PL 116-136, 134 Stat. 281, 362 (2020-03-27)	N
506F	356f	Hospital repackaging of drugs in shortage	PL 112-144, 126 Stat. 993, 1106 (2012-07-09)	Not amended	N
506G	356g	Standards for regenerative medicine and regenerative advanced therapies	PL 114-255, 130 Stat. 1033, 1104 (2016-12-13)	PL 115-52, 131 Stat. 1005, 1076 (2017-08-18)	N
506H	356h	Competitive generic therapies	PL 115-52, 131 Stat. 1005, 1069 (2017-08-18)	Not amended	N
506I	356i	Prompt reports of marketing status	PL 115-52, 131 Stat. 1005, 1071 (2017-08-18)	PL 117-328, 136 Stat. 4459, 5808 (2022-12-29)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
506J	356j	Discontinuance or interruption in the production of medical devices	PL 116-136, 134 Stat. 281, 363 (2020-03-27)	PL 117-328, 136 Stat. 4459, 5805 (2022-12-29)	N
506K	356k	Platform technologies	PL 117-328, 136 Stat. 4459, 5798 (2022-12-29)	Not amended	N
506L	356*l*	Advanced manufacturing technologies designation program	PL 117-328, 136 Stat. 4459, 5826 (2022-12-29)	Not amended	N
507	357	Qualification of drug development tools.	PL 114-255, 130 Stat. 1033, 1086 (2016-12-13)	PL 116-22, 133 Stat. 905, 964 (2019-06-24)	N
508	358	Authority to designate official names	PL 87-781, 76 Stat. 780, 789 (1962-10-10)	PL 103-80, 107 Stat. 773, 777 (1993-08-13)	N
509	359	Nonapplicability of subchapter to cosmetics	PL 87-781, 76 Stat. 780, 791 (1962-10-10)	Not amended	N
510	360	Registration of producers of drugs or devices	PL 87-781, 76 Stat. 780, 794 (1962-10-10)	PL 117-328, 136 Stat. 4459, 5803, 5806, 5836, 5872, 5875 (2022-12-29)	Y
511	360a	Clinical trial guidance for antibiotic drugs	PL 110-85, 121 Stat. 823, 951 (2007-09-27)	Not amended	N
N/A	360a-1	Clinical trials	PL 112-144, 126 Stat. 993, 1080 (2012-07-09)	Not amended	N
511A	360a-2	Susceptibility test interpretive criteria for microorganisms	PL 114-255, 130 Stat. 1033, 1114 (2016-12-13)	Not amended	N
512	360b	New animal drugs	PL 90-399, 82 Stat. 342, 343 (1968-07-13)	PL 117-9, 135 Stat. 256, 257 (2021-04-23)	Y
512A	360b-1	Priority zoonotic animal drugs	PL 116-136, 134 Stat. 281, 384 (2020-03-27)	Not amended	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
513	360c	Classification of devices intended for human use	PL 94-295, 90 Stat. 539, 540 (1976-05-28)	PL 117-328, 136 Stat. 4459, 5831 (2022-12-29)	Y
N/A	360c-1	Reporting	PL 112-144, 126 Stat. 993, 1059 (2012-07-09)	Not amended	N
514	360d	Performance standards	PL 94-295, 90 Stat. 539, 546 (1976-05-28)	PL 117-180, 136 Stat. 2114, 2153 (2022-09-30)	N
515	360e	Premarket approval	PL 94-295, 90 Stat. 539, 552 (1976-05-28)	PL 117-328, 136 Stat. 4459, 5836 (2022-12-29)	Y
515A	360e-1	Pediatric uses of devices	PL 110-85, 121 Stat. 823, 859 (2007-09-27)	PL 115-52, 131 Stat. 1005, 1037 (2017-08-18)	N
515B	360e-3	Breakthrough devices	PL 114-255, 130 Stat. 1033, 1121 (2016-12-13)	PL 115-52, 131 Stat. 1005, 1076 (2017-08-18)	Y
515C	360e-4	Predetermined change control plans for devices	PL 117-328, 136 Stat. 4459, 5835 (2022-12-29)	Not amended	N
516	360f	Banned devices	PL 94-295, 90 Stat. 539, 560 (1976-05-28)	PL 117-328, 136 Stat. 4459, 5834 (2022-12-29)	N
517	360g	Judicial review	PL 94-295, 90 Stat. 539, 560 (1976-05-28)	PL 112-144, 126 Stat. 993, 1056 (2012-07-09)	N
517A	360g-1	Agency documentation and review of significant decisions regarding devices	PL 112-144, 126 Stat. 993, 1051 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5836 (2022-12-29)	N
N/A	360g-2	Third party data transparency	PL 117-328, 136 Stat. 4459, 5834, (2022-12-29)	Not amended	N
518	360h	Notification and other remedies	PL 94-295, 90 Stat. 539, 562 (1976-05-28)	PL 102-300, 106 Stat. 238, 239 (1992-06-16)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
518A	360h-1	Program to improve the device recall system	PL 112-144, 126 Stat. 993, 1053 (2012-07-09)	PL 114-255, 130 Stat. 1033, 1154 (2016-12-13)	N
519	360i	Sec. 519 Sec. 360i - Records and reports on devices	PL 94-295, 90 Stat. 539, 564 (1976-05-28)	PL 115-52, 131 Stat. 1005, 1062 (2017-08-18)	N
520	360j	General provisions respecting control of devices intended for human use	PL 94-295, 90 Stat. 539, 565 (1976-05-28)	PL 117-328, 136 Stat. 4459, 5807, 5861 (2022-12-29)	Y
521	360k	State and local requirements respecting devices	PL 94-295, 90 Stat. 539, 574 (1976-05-28)	Not amended	Y
522	360l	Postmarket surveillance	PL 101-629, 104 Stat. 4511, 4521 (1990-11-28)	PL 112-144, 126 Stat. 993, 1062 (2012-07-09)	N
523	360m	Accredited persons	PL 105-115, 111 Stat. 2296, 2342 (1997-11-21)	PL 117-328, 136 Stat. 4459, 5808 (2022-12-29)	N
524	360n	Priority review to encourage treatments for tropical diseases	PL 110-85, 121 Stat. 823, 972 (2007-09-27)	PL 117-9, 135 Stat. 256, 257 (2021-04-23)	N
524A	360n-1	Priority review for qualified infectious disease products	PL 112-144, 126 Stat. 993, 1079 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5826 (2022-12-29)	N
524B	360n-2	Ensuring cybersecurity of devices	PL 117-328, 136 Stat. 4459, 5832 (2022-12-29)	Not amended	N
Subchapter B (525–529A)	*Part B (360aa–360ff-1)*	*Drugs for Rare Diseases or Conditions*			
525	360aa	Recommendations for investigations of drugs for rare diseases or conditions	PL 97-414, 96 Stat. 2049, 2049 (1983-01-04)	PL 105-115, 111 Stat. 2296, 2325 (1997-11-21)	N
526	360bb	Designation of drugs for rare diseases or conditions	PL 97-414, 96 Stat. 2049, 2050 (1983-01-04)	PL 105-115, 111 Stat. 2296, 2326 (1997-11-21)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
527	360cc	Protection for drugs for rare diseases or conditions	PL 97-414, 96 Stat. 2049, 2050 (1983-01-04)	PL 116-260, 134 Stat. 1182, 2933 (2020-12-27)	N
528	360dd	Open protocols for investigations of drugs for rare diseases or conditions	PL 97-414, 96 Stat. 2049, 2051 (1983-01-04)	Not amended	N
N/A	360ee	Grants and contracts for development of drugs for rare diseases and conditions	PL 97-414, 96 Stat. 2049, 2056 (1983-01-04)	PL 117-328, 136 Stat. 4459, 5808 (2022-12-29)	N
N/A	360ee-1	FDA rare neurodegenerative disease grant program	PL 117-79, 135 Stat. 1533, 1537 (2021-12-23)	Not amended	N
529	360ff	Priority review to encourage treatments for rare pediatric diseases	PL 112-144, 126 Stat. 993, 1094 (2012-07-09)	PL 117-9, 135 Stat. 256, 257 (2021-04-23)	N
529A	360ff-1	Targeted drugs for rare diseases	PL 114-255, 130 Stat. 1033, 1091 (2016-12-13)	Not amended	N
Subchapter C (531–542)	*Part C (360hh–360ss)*	*Electronic Product Radiation Control*			
N/A	360gg.	Declaration of purpose	PL 90-602, 82 Stat. 1173, 1173 (1968-10-18)	*Repealed by* PL 101-629, 140 Stat. 4511, 4530 (1990-11-28)	N
531	360hh	Definitions	PL 90-602, 82 Stat. 1173, 1174 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
532	360ii	Program of control	PL 90-602, 82 Stat. 1173, 1174 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
533	360jj	Studies by Secretary	PL 90-602, 82 Stat. 1173, 1176 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
534	360kk	Performance standards for electronic products	PL 90-602, 82 Stat. 1173, 1177 (1968-10-18)	PL 103-80, 107 Stat. 773, 778 (1993-08-13)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
535	360ll	Notification of defects in and repair or replacement of electronic products	PL 90-602, 82 Stat. 1173, 1180 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
536	360mm	Imports	PL 90-602, 82 Stat. 1173, 1181 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
537	360nn	Inspection, records, and reports	PL 90-602, 82 Stat. 1173, 1182 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
538	360oo	Prohibited acts	PL 90-602, 82 Stat. 1173, 1184 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
539	360pp	Enforcement	PL 90-602, 82 Stat. 1173, 1184 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
540	360qq	Annual report	PL 90-602, 82 Stat. 1173, 1185 (1968-10-18)	*Repealed by* PL 105-362, 112 Stat. 3280, 3285 (1998-11-10)	N
541	360rr	Federal-State cooperation	PL 90-602, 82 Stat. 1173, 1186 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
542	360ss	State standards	PL 90-602, 82 Stat. 1173, 1186 (1968-10-18)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N
Subchapter D (551–557)	*Part D (360aaa–aaa-6)*	*Dissemination of Treatment Information* [now omitted from U.S. code as sunset date has passed]		PL 105-115, 111 Stat. 2296, 2364 (1997-11-27)	
551	360aaa	Requirements for dissemination of treatment information on drugs or devices	PL 105-115, 111 Stat. 2296, 2356 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N
552	360aaa-1	Information authorized to be disseminated	PL 105-115, 111 Stat. 2296, 2358 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
553	360aaa-2	Establishment of list of articles and publications disseminated and list of providers that received articles and reference publications	PL 105-115, 111 Stat. 2296, 2359 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N
554	360aaa-3	Requirement regarding submission of supplemental application for new use; exemption from requirement	PL 105-115, 111 Stat. 2296, 2359 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N
555	360aaa-4	Corrective actions; cessation of dissemination	PL 105-115, 111 Stat. 2296, 2361 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N
556	360aaa-5	Definitions	PL 105-115, 111 Stat. 2296, 2362 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N
557	360aaa-6	Rules of construction	PL 105-115, 111 Stat. 2296, 2363 (1997-11-21)	No longer effective per statutory sunset date of 2006-09-30	N
Subchapter E (561–569D)	*Part E (360bbb–360bbb-8d)*	*General Provisions Relating to Drugs and Devices*			
561	360bbb	Expanded access to unapproved therapies and diagnostics	PL 105-115, 111 Stat. 2296, 2365 (1997-11-21)	PL 109-482, 120 Stat. 3675, 3685 (2007-01-15)	Y
561A	360bbb-0	Expanded access policy required for investigational drugs	PL 114-255, 130 Stat. 1033, 1100 (2016-12-13)	PL 115-52, 131 Stat. 1005, 1053 (2017-08-18)	N
561B	360bbb-0a	Investigational drugs for use by eligible patients	PL 115-176, 132 Stat. 1372, 1372 (2018-05-30)	Not amended	N
562	360bbb-1	Dispute resolution	PL 105-115, 111 Stat. 2296, 2368 (1997-11-21)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
563	360bbb-2	Classification of products	PL 105-115, 111 Stat. 2296, 2378 (1997-11-21)	Not amended	Y
564	360bbb-3	Authorization for medical products for use in emergencies	PL 108-136, 117 Stat. 1392, 1684 (2003-11-24)	PL 117-328, 136 Stat. 4459, 5802 (2022-12-29)	Y
564A	360bbb-3a	Emergency use of medical products	PL 113-5, 127 Stat. 161, 183 (2013-03-13)	PL 116-22, 133 Stat. 905, 964 (2019-06-24)	Y
564B	360bbb-3b	Products held for emergency use	PL 113-5, 127 Stat. 161, 185 (2013-03-13)	PL 116-22, 133 Stat. 905, 964 (2019-06-24)	Y
N/A	360bbb-3c	Expedited development and review of medical products for emergency uses	PL 115-92, 131 Stat. 2023, 2023 (2017-12-12)	Not amended	N
565	360bbb-4	Countermeasure development, review, and technical assistance	PL 109-417, 120 Stat. 2831, 2875 (2006-12-19)	PL 117-328, 136 Stat. 4459, 5796 (2022-12-29)	N
565A	360bbb-4a	Priority review to encourage treatments for agents that present national security threats	PL 114-255, 130 Stat. 1033, 1144 (2016-12-13)	PL 117-9, 135 Stat. 256, 258 (2021-04-23)	N
565B	360bbb-4b	Medical countermeasure master files	PL 116-22, 133 Stat. 905, 953 (2019-06-24)	Not amended	N
566	360bbb-5	Critical Path Public-Private Partnerships	PL 110-85, 121 Stat. 823, 898 (2007-09-27)	PL 117-328, 136 Stat. 4459, 5807 (2022-12-29)	N
566A	360bbb-5a	Emerging technology program	PL 117-328, 136 Stat. 4459, 5814 (2022-12-29)	Not amended	N
567	360bbb-6	Risk communication	PL 110-85, 121 Stat. 823, 960 (2007-09-27)	PL 117-286, 136 Stat. 4196, 4323 (2022-12-27)	N
568	360bbb-7	Notification	PL 112-144, 126 Stat. 993, 1075 (2012-07-09)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
569	360bbb-8	Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments	PL 112-144, 126 Stat. 993, 1088 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5812 (2022-12-29)	N
569A	360bbb-8a	Optimizing global clinical trials	PL 112-144, 126 Stat. 993, 1113 (2012-07-09)	PL 114-255, 130 Stat. 1033, 1154 (2016-12-13)	N
569B	360bbb-8b	Use of clinical investigation data from outside the United States	PL 112-144, 126 Stat. 993, 1123 (2012-07-09)	PL 114-255, 130 Stat. 1033, 1155 (2016-12-13)	N
569C	360bbb-8c	Patient participation in medical product discussion	PL 112-144, 126 Stat. 993, 1124 (2012-07-09)	PL 115-52, 131 Stat. 1005, 1048 (2017-08-18)	N
569D	360bbb-8d	Notification, nondistribution, and recall of controlled substances	PL 115-271, 132 Stat. 3894, 3935 (2018-10-24)	Not amended	N
Subchapter F (571–573)	*Part F (360-ccc–360ccc-2)*	*New Animal Drugs for Minor Use and Minor Species*			
571	360ccc	Conditional approval of new animal drugs for minor use and minor species and certain new animal drugs	PL 108-282, 118 Stat. 891, 892 (2004-08-02)	PL 115-234, 132 Stat. 2427, 2436 (2018-08-14)	Y
572	360ccc-1	Index of legally marketed unapproved new animal drugs for minor species	PL 108-282, 118 Stat. 891, 896 (2004-08-02)	PL 117-286, 136 Stat. 4196, 4323 (2022-12-27)	Y
573	360ccc-2	Designated new animal drugs for minor use or minor species	PL 108-282, 118 Stat. 891, 900 (2004-08-02)	PL 114-89, 129 Stat. 698, 700 (2015-11-25)	Y
Subchapter G (575–577)	*Part G (360ddd–360ddd-2)*	*Medical Gases*			
575	360ddd	Definitions	PL 112-144, 126 Stat. 993, 1108 (2012-07-09)	PL 114-255, 130 Stat. 1033, 1155 (2016-12-13)	N
576	360ddd-1	Regulation of medical gases	PL 112-144, 126 Stat. 993, 1109 (2012-07-09)	PL 114-255, 130 Stat. 1033, 1155 (2016-12-13)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
577	360ddd-2	Inapplicability of drug fees to designated medical gases	PL 112-144, 126 Stat. 993, 1111 (2012-07-09)	PL 114-255, 130 Stat. 1033, 1155 (2016-12-13)	N
Subchapter H (581–585)	*Part H (360eee–360eee-4)*	*Pharmaceutical Distribution Supply Chain*			
581	360eee	Definitions	PL 113-54, 127 Stat. 587, 599 (2013-11-27)	Not amended	N
582	360eee-1	Requirements	PL 113-54, 127 Stat. 587, 605, 623 (2013-11-27)	Not amended	N
583	360eee-2	National standards for prescription drug wholesale distributors	PL 113-54, 127 Stat. 587, 634 (2013-11-27)	Not amended	N
584	360eee-3	National standards for third-party logistics providers	PL 113-54, 127 Stat. 587, 636 (2013-11-27)	Not amended	N
585	360eee-4	Uniform national policy	PL 113-54, 127 Stat. 587, 638 (2013-11-27)	Not amended	N
Subchapter I (586–586H)	*Part I (360fff –360fff-8)*	*Nonprescription Sunscreen and Other Active Ingredients*			
586	360fff	Definitions	PL 113-195, 128 Stat. 2035, 2035 (2014-11-26)	PL 116-136 provides for sunset at end of FY 2022	N
586A	360fff-1	Submission of requests	PL 113-195, 128 Stat. 2035, 2036 (2014-11-26)	PL 116-136 provides for sunset at end of FY 2022	N
586B	360fff-2	Eligibility determinations; data submission; filing	PL 113-195, 128 Stat. 2035, 2036 (2014-11-26)	PL 116-136 provides for sunset at end of FY 2022	N
586C	360fff-3	GRASE determination	PL 113-195, 128 Stat. 2035, 2039 (2014-11-26)	PL 116-136, 134 Stat. 281, 455 (2020-03-27); PL 116-	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
				136 also provides for sunset at end of FY 2022	
586D	360fff-4	Guidance; other provisions	PL 113-195, 128 Stat. 2035, 2044 (2014-11-26)	PL 116-136 provides for sunset at end of FY 2022	N
586E	360fff-5	Sunscreen monograph	PL 113-195, 128 Stat. 2035, 2045 (2014-11-26)	*Repealed by* PL 116-136, 134 Stat. 281, 456 (2020-03-27)	N
586F	360fff-6	Non-sunscreen time and extent applications	PL 113-195, 128 Stat. 2035, 2044 (2014-11-26)	PL 116-136, 134 Stat. 281, 457 (2020-03-27) amends statutory note; PL 116-136 also provides for sunset at end of FY 2022	N
586G	360fff-7	Report	PL 113-195, 128 Stat. 2035, 2050 (2014-11-26)	PL 116-136 provides for sunset at end of FY 2022	N
586H	360fff-8	Sunset	PL 116-136, 134 Stat. 281, 456 (2020-03-27)	Not amended	N
Chapter VI (601–614)	**Subchapter VI (361–364j)**	**Cosmetics**			
601	361	Adulterated cosmetics	PL 75-717, 52 Stat. 1040, 1054 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5858 (2022-12-29)	Y
602	362	Misbranded cosmetics	PL 75-717, 52 Stat. 1040, 1054 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5858 (2022-12-29)	Y
603	363	Regulations making exemptions	PL 75-717, 52 Stat. 1040, 1054 (1938-06-25)	Not amended	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
604	364	Definitions	PL 117-328, 136 Stat. 4459, 5847 (2022-12-29)	Not amended	Y
605	364a	Adverse events	PL 117-328, 136 Stat. 4459, 5848 (2022-12-29)	Not amended	Y
606	364b	GMP	PL 117-328, 136 Stat. 4459, 5850 (2022-12-29)	Not amended	Y
607	364c	Registration and product listing	PL 117-328, 136 Stat. 4459, 5851, (2022-12-29)	Not amended	Y
608	364d	Safety substantiation	PL 117-328, 136 Stat. 4459, 5854 (2022-12-29)	Not amended	Y
609	364e	Labeling	PL 117-328, 136 Stat. 4459, 5854 (2022-12-29)	Not amended	Y
610	364f	Records	PL 117-328, 136 Stat. 4459, 5855 (2022-12-29)	Not amended	Y
611	364g	Mandatory recall authority	PL 117-328, 136 Stat. 4459, 5855 (2022-12-29)	Not amended	Y
612	364h	Small businesses	PL 117-328, 136 Stat. 4459, 5857 (2022-12-29)	Not amended	Y
613	364i	Exemption for certain products and facilities	PL 117-328, 136 Stat. 4459, 5857 (2022-12-29)	Not amended	Y
614	364j	Preemption	PL 117-328, 136 Stat. 4459, 5857 (2022-12-29)	Not amended	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
Chapter VII (701–772)	**Subchapter VII (sections 371–379dd-2)**	**General Authority**			
Subchapter A (701–715)	*Part A (371–379d-5)*	*General Administrative Provisions*			
701	371	Regulations and hearings	PL 75-717, 52 Stat. 1040, 1055 (1938-06-25)	PL 112-144, 126 Stat. 993, 1063 (2012-07-09)	Y
702	372	Examinations and investigations	PL 75-717, 52 Stat. 1040, 1056 (1938-06-25)	PL 111-31, 123 Stat. 1776, 1837 (2009-06-22)	Y
702A	372a	*[Transferred to FFDCA § 706; 21 U.S.C. 376]*	See info for FFDCA § 706	*Transferred by* PL 102-571, 106 Stat. 4491, 4498 (1992-10-29)	N
703	373	Records	PL 75-717, 52 Stat. 1040, 1057 (1938-06-25)	PL 111-31, 123 Stat. 1776, 1837 (2009-06-22)	Y
704	374	Inspection	PL 75-717, 52 Stat. 1040, 1057 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5806, 5807, 5859, 5869, 5872 (2022-12-29)	Y
N/A	374a	Inspections relating to food allergens	PL 108-282, 118 Stat. 891, 909 (2004-08-02)	Not amended	N
705	375	Publicity	PL 75-717, 52 Stat. 1040, 1057 (1938-06-25)	PL 111-31, 123 Stat. 1776, 1837 (2009-06-22)	Y
706	376	Examination of sea food on request of packer; marking food with results; fees; penalties	PL 73-451, 48 Stat 1204, 1204 (1934-06-22)	PL 103-80, 107 Stat. 773, 779 (1993-08-13)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
N/A	377	Revision of United States Pharmacopoeia; development of analysis and mechanical and physical tests	PL 78-135, 57 Stat. 494, 500 (1943-07-12)	Not amended	N
707	378	Advertising of foods	PL 94-278, 90 Stat. 401, 412 (1976-04-22)	Not amended	N
708	379	Confidential information	PL 94-295, 90 Stat. 539, 582 (1976-05-28)	PL 112-144, 126 Stat. 993, 1070 (2012-07-09)	N
709	379a	Presumption of existence of jurisdiction	PL 94-295, 90 Stat. 539, 583 (1976-05-28)	PL 111-31, 123 Stat. 1776, 1837 (2009-06-22)	Y
710	379b	Consolidated administrative and laboratory facility	PL 101-635, 104 Stat. 4583, 4583 (1990-11-28)	Not amended	N
[formerly 711]	379c	*[Transferred to FFDCA 731; 21 U.S.C. 379f]*	See info for FFDCA § 731	*Transferred by* PL 102-571, 106 Stat. 4491, 4499 (1992-10-29)	N
711	379d	Automation of Food and Drug Administration	PL 101-635, 104 Stat. 4583, 4585 (1990-11-28)	PL 102-571, 106 Stat. 4491, 4498 (1992-10-29)	N
712	379d-1	Conflicts of interest	PL 110-85, 121 Stat. 823, 900 (2007-09-27)	PL 117-286, 136 Stat. 4196, 4323, 4357 (2022-12-27)	N
713	379d-2	Policy on the review and clearance of scientific articles published by FDA employees	PL 110-85, 121 Stat. 823, 971 (2007-09-27)	Not amended	N
714	379d-3	Streamlined hiring authority	PL 112-144, 126 Stat. 993, 1007 (2012-07-09)	PL 115-52, 131 Stat. 1005, 1013 (2017-08-18)	N
714A	379d-3a	Hiring authority for scientific, technical, and professional personnel	PL 114-255, 130 Stat. 1033, 1134 (2016-12-13)	PL 117-328, 136 Stat. 4459, 5879 (2022-12-29)	N
714B	379d-3b	Strategic workforce plan and report	PL 117-328, 136 Stat. 4459, 5878 (2022-12-29)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
715	379d-4	Reporting requirements	PL 112-144, 126 Stat. 993, 1025, 1039 (2012-07-09)	Not amended	N
N/A	379d-5	Guidance document regarding product promotion using the Internet	PL 112-144, 126 Stat. 993, 1112 (2012-07-09)	Not amended	N
Subchapter B (371)	*Part B (379e)*	*Colors*			
721	379e	Listing and certification of color additives for foods, drugs, devices, and cosmetics	PL 86-618, 74 Stat. 397, 399 (1960-07-12) (color additives); PL 75-717, 52 Stat. 1040, 1058 (1938-06-25) (coal-tar colors)	PL 103-80, 107 Stat. 773, 778 (1993-08-13)	Y
Subchapter C (731–744N)	*Part C (379f–379j-73)*	*Fees* [Note: many of the user-fee provisions in this Part have sunset dates; to avoid cluttering the chart these sunset dates are not individually listed.]			
Part 1 (739)	*Subpart 1 379f)*	*Freedom of information fees*			
731	379f	Recovery and retention of fees for freedom of information requests	PL 101-635, 104 Stat. 4583, 4584 (1990-11-28)	PL 102-571, 106 Stat. 4491, 4499 (1992-10-29)	N
Part 2 (735–737B)	*Subpart 2 (379g–379h-2)*	*Fees relating to drugs*			
735	379g	Definitions	PL 102-571, 106 Stat. 4491, 4491 (1992-10-29)	PL 117-180, 136 Stat 2114, 2140 (2022-09-30)	N
736	379h	Authority to assess and use drug fees	PL 102-571, 106 Stat. 4491, 4494 (1992-10-29)	PL 117-328, 136 Stat. 4459, 5880 (2022-12-29)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
736A	379h-1	Fees relating to advisory review of prescription drug television advertising	PL 110-85, 121 Stat. 823, 832 (2007-09-27)	Not amended	N
737B	379h-2	Reauthorization; reporting requirements	PL 110-85, 121 Stat. 823, 840 (2007-09-27)	PL 117-328, 136 Stat. 4459, 5883 (2022-12-29)	N
Part 3 (737–738A)	*Subpart 3 (379i–379j-1)*	*Fees relating to devices*			
737	379i	Definitions	PL 107-250, 116 Stat. 1588, 1589 (2002-10-26)	PL 117-180, 136 Stat. 2114, 2148 (2022-09-30)	N
738	379j	Authority to assess and use device fees	PL 107-250, 116 Stat. 1588, 1591 (2002-10-26)	PL 117-328, 136 Stat. 4459, 5836, 5882 (2022-12-29)	N
738A	379j-1	Reauthorization; reporting requirements	PL 110-85, 121 Stat. 823, 850 (2007-09-27)	PL 117-328, 136 Stat. 4459, 5884 (2022-12-29)	N
Part 4 (739–740A)	*Subpart 4 (379j-11–379j-13)*	*Fees relating to animal drugs*			
739	379j-11	Definitions	PL 108-130, 117 Stat. 1361, 1361 (2003-11-18)	PL 118-15, 137 Stat. 71, 86 (2023-09-30)	N
740	379j-12	Authority to assess and use animal drug fees	PL 108-130, 117 Stat. 1361, 1363 (2003-11-18)	PL 118-15, 137 Stat. 71, 87 (2023-09-30)	N
740A	379j-13	Reauthorization; reporting requirements	PL 110-316, 122 Stat. 3509, 3511 (2008-08-14)	PL 118-15, 137 Stat. 71, 89 (2023-09-30)	N
Part 5 (741–742)	*Subpart 5 (379j-21–379j-22)*	*Fees relating to generic new animal drugs*			

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
741	379j-21	Authority to assess and use generic new animal drug fees	PL 110-316, 122 Stat. 3509, (2008-08-14)	PL 118-15, 137 Stat. 71, 90 (2023-09-30)	N
742	379j-22	Reauthorization; reporting requirements	PL 110-316, 122 Stat. 3509, 3522 (2008-08-14)	PL 118-15, 137 Stat. 71, 93 (2023-09-30)	N
Part 6 (743)	*Subpart 6 (379j-31)*	*Fees related to food*			
743	379j-31	Authority to collect and use fees	PL 111-353, 124 Stat. 3885, 3906 (2011-01-04)	Not amended	N
Part 7 (744A–744C)	*Subpart 7 (379j-41–379j-43)*	*Fees relating to generic drugs*			
744A	379j-41	Definitions	PL 112-144, 126 Stat. 993, 1008 (2012-07-09)	PL 115-52, 131 Stat. 1005, 1020 (2017-08-18)	N
744B	379j-42	Authority to assess and use human generic drug fees	PL 112-144, 126 Stat. 993, 1011 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5881 (2022-12-29)	N
744C	379j-43	Reauthorization; reporting requirements	PL 112-144, 126 Stat. 993, 1022 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5885 (2022-12-29)	N
Part 8 (744G–744I)	*Subpart 8 (379j-51–379j-53)*	*Fees relating to biosimilar biological products*			
744G	379j-51	Definitions	PL 112-144, 126 Stat. 993, 1026 (2012-07-09)	PL 117-180, 136 Stat. 2114, 2160 (2022-09-30)	N
744H	Sec. 379j-52	Authority to assess and use biosimilar biological product fees	PL 112-144, 126 Stat. 993, 1029 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5880 (2022-12-29)	N
744I	Sec. 379j-53	Reauthorization; reporting requirements	PL 112-144, 126 Stat. 993, 1037 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5886 (2022-12-29)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
Part 9 (744J–744K)	*Subpart 9 (379j-61–379j-62)*	*Fees relating to outsourcing facilities*			
744J	Sec. 379j-61	Definitions	PL 113-54, 127 Stat. 587, 593 (2013-11-27)	Not amended	N
744K	Sec. 379j-62	Authority to assess and use outsourcing facility fees	PL 113-54, 127 Stat. 587, 594 (2013-11-27)	Not amended	N
Part 10 (744L–744N)	*Subpart 10 (379j-71–379j-73)*	*Fees relating to over-the-counter drugs*			
744L	379j-71	Definitions	PL 116-136, 134 Stat. 281, 459 (2020-03-27)	Not amended	N
744M	379j-72	Authority to assess and use OTC monograph fees	PL 116-136, 134 Stat. 281, 461 (2020-03-27)	Not amended	N
744N	379j-73	Reauthorization; reporting requirements	PL 116-136, 134 Stat. 281, 468 (2020-03-27)	Not amended	N
Subchapter D (745–746)	*Part D (379k–379l))*	*Information and Education*			
745	379k	Information system	PL 105-115, 111 Stat. 2296, 2370 (1997-11-21)	PL 110-316, 122 Stat. 3509, 3515 (2008-08-14)	N
745A	379k-1	Electronic format for submissions	PL 112-144, 126 Stat. 993, 1123 (2012-07-09)	PL 115-52, 131 Stat. 1005, 1019 (2017-08-18)	N
746	379l	Education	PL 105-115, 111 Stat. 2296, 2371 (1997-11-21)	PL 110-316, 122 Stat. 3509, 3515 (2008-08-14)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
Subchapter E (749)	*Part E (379o)*	*Environmental Impact Review*			
749	379*o*	Environmental impact	PL 105-115, 111 Stat. 2296, 2373 (1997-11-21)	PL 110-316, 122 Stat. 3509, 3515 (2008-08-14)	N
Subchapter F (751–52)	*Part F (379r–379s)*	*National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packaging of Cosmetics*			
751	379r	National uniformity for nonprescription drugs	PL 105-115, 111 Stat. 2296, 2373 (1997-11-21)	PL 116-136, 134 Stat. 281, 454 (2020-03-27)	N
752	379s	Preemption for labeling or packaging of cosmetics	PL 105-115, 111 Stat. 2296, 2376 (1997-11-21)	Not amended	N
Subchapter G (756)	*Part G (379v)*	*Safety Reports*			
756	379v	Safety report disclaimers	PL 105-115, 111 Stat. 2296, 2379 (1997-11-21)	Not amended	N
Subchapter H (760–61)	*Part H (379aa–379aa-1)*	*Serious Adverse Event Reports*			
760	379aa	Serious adverse event reporting for nonprescription drugs	PL 109-462, 120 Stat. 3469, 3469 (2006-12-22)	Not amended	N
761	379aa-1	Serious adverse event reporting for dietary supplements	PL 109-462, 120 Stat. 3469, 3472 (2006-12-22)	Not amended	N
Subchapter I (770–772)	*Part I (379dd–379dd-2)*	*Reagan-Udall Foundation for the Food and Drug Administration*			
770	379dd	Establishment and functions of the Foundation	PL 110-85, 121 Stat. 823, 890 (2007-09-27)	PL 117-101, 136 Stat. 47, 47 (2022-03-15)	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
771	379dd-1	Location of Foundation	PL 110-85, 121 Stat. 823, 897 (2007-09-27)	Not amended	N
772	379dd-2	Activities of the Food and Drug Administration	PL 110-85, 121 Stat. 823, 897 (2007-09-27)	Not amended	N
Chapter VII (801–809)	**Subchapter VIII (381–384g)**	**Imports and Exports**			
801	381	Imports and exports	PL 75-717, 52 Stat. 1040, 1058 (1938-06-25)	PL 117-328, 136 Stat. 4459, 5832, 5858 (2022-12-29)	Y
802	382	Exports of certain unapproved products	PL 99-660, 100 Stat. 3743, 3743 (1986-11-14)	PL 105-115, 111 Stat. 2296, 2326 (1997-11-21)	N
803	383	Office of International Relations	PL 101-629, 104 Stat. 4511, 4525 (1990-11-28)	PL 112-144, 126 Stat. 993, 1059 (2012-07-09)	Y
804	384	Importation of prescription drugs	PL 108-173, 117 Stat. 2066, 2464 (2003-12-08)	PL 114-125, 130 Stat. 122, 210 (2016-02-24)	Y
805	384a	Foreign supplier verification program	PL 111-353, 124 Stat. 3885, 3953 (2011-01-04)	Not amended	Y
806	384b	Voluntary qualified importer program	PL 111-353, 124 Stat. 3885, 3955 (2011-01-04)	Not amended	Y
807	384c	Inspection of foreign food facilities	PL 111-353, 124 Stat. 3885, 3958 (2011-01-04)	Not amended	Y
808	384d	Accreditation of third-party auditors	PL 111-353, 124 Stat. 3885, 3959 (2011-01-04)	Not amended	Y
809	384e	Recognition of foreign government inspections	PL 112-144, 126 Stat. 993, 1072 (2012-07-09)	PL 117-328, 136 Stat. 4459, 5872 (2022-12-29)	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
N/A	384f	Strengthening FDA and CBP coordination and capacity	PL 115-271, 132 Stat. 3894, 3937 (2018-10-24)	Not amended	N
N/A	384g	Restricting entrance of illicit drugs	PL 115-271, 132 Stat. 3894, 3938 (2018-10-24)	Not amended	N
Chapter IX (901–920)	**Subchapter IX (387–387v)**	**Tobacco Products**			
900	387	Definitions	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	Not amended	Y
901	387a	FDA authority over tobacco products	PL 111-31, 123 Stat. 1776, 1786 (2009-06-22)	PL 117-103, 136 Stat. 49, 789 (2022-03-15)	Y
N/A	387a-1	Final rule	PL 111-31, 123 Stat. 1776, 1830 (2009-06-22)	Not amended	N
902	387b	Adulterated tobacco products	PL 111-31, 123 Stat. 1776, 1787 (2009-06-22)	Not amended	Y
903	387c	Misbranded tobacco products	PL 111-31, 123 Stat. 1776, 1788 (2009-06-22)	PL 116-94, 133 Stat. 2534, 3124 (2019-12-20)	Y
904	387d	Submission of health information to the Secretary	PL 111-31, 123 Stat. 1776, 1790 (2009-06-22)	Not amended	N
905	387e	Annual registration	PL 111-31, 123 Stat. 1776, 1792 (2009-06-22)	Not amended	Y
906	387f	General provisions respecting control of tobacco products	PL 111-31, 123 Stat. 1776, 1795 (2009-06-22)	PL 116-94, 133 Stat. 2534, 3123 (2019-12-20)	Y
N/A	387f-1	Enforcement action plan for advertising and promotion restrictions	PL 111-31, 123 Stat. 1776, 1841 (2009-06-22)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
907	387g	Tobacco product standards	PL 111-31, 123 Stat. 1776, 1799 (2009-06-22)	PL 117-103, 136 Stat. 49, 790 (2022-03-15)	Y
908	387h	Notification and other remedies	PL 111-31, 123 Stat. 1776, 1804 (2009-06-22)	Not amended	N
909	387i	Records and reports on tobacco products	PL 111-31, 123 Stat. 1776, 1805 (2009-06-22)	Not amended	N
910	387j	Application for review of certain tobacco products	PL 111-31, 123 Stat. 1776, 1807 (2009-06-22)	Not amended	Y
911	387k	Modified risk tobacco products	PL 111-31, 123 Stat. 1776, 1812 (2009-06-22)	Not amended	Y
912	387l	Judicial review	PL 111-31, 123 Stat. 1776, 1819 (2009-06-22)	Not amended	N
913	387m	Equal treatment of retail outlets	PL 111-31, 123 Stat. 1776, 1820 (2009-06-22)	Not amended	N
914	387n	Jurisdiction of and coordination with the Federal Trade Commission	PL 111-31, 123 Stat. 1776, 1820 (2009-06-22)	Not amended	N
915	387o	Regulation requirement	PL 111-31, 123 Stat. 1776, 1820 (2009-06-22)	Not amended	N
916	387p	Preservation of State and local authority	PL 111-31, 123 Stat. 1776, 1823 (2009-06-22)	Not amended	N
917	387q	Tobacco Products Scientific Advisory Committee	PL 111-31, 123 Stat. 1776, 1824 (2009-06-22)	PL 117-286, 136 Stat. 4196, 4323 (2022-12-27)	N
918	387r	Drug products used to treat tobacco dependence	PL 111-31, 123 Stat. 1776, 1825 (2009-06-22)	Not amended	N

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
919	387s	User fees	PL 111-31, 123 Stat. 1776, 1826 (2009-06-22)	Not amended	N
920	387t	Labeling, recordkeeping, records inspection	PL 111-31, 123 Stat. 1776, 1850 (2009-06-22)	Not amended	N
N/A	387u	Studies of progress and effectiveness	PL 111-31, 123 Stat. 1776, 1841 (2009-06-22)	Not amended	N
N/A	387v	Reporting on tobacco regulation activities	PL 117-103, 136 Stat. 49, 790 (2022-03-15)	Not amended	N
Chapter X (1001–1013)	**Subchapter X (391–399i)**	**Miscellaneous**			
1001	391	Separability clause	PL 75-717, 52 Stat. 1040, 1059 (1938-06-25)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	Y
1002	392	Exemption of meats and meat food products	PL 75-717, 52 Stat. 1040, 1059 (1938-06-25)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	Y
1003	393	Food and Drug Administration	PL 100-607, 102 Stat. 3048, 3121 (1988-11-04)	PL 111-353, 124 Stat. 3885, 3925 (2011-01-04)	Y
1003a	393a	Office of Pediatric Therapeutics	PL 107-109, 115 Stat. 1408, 1414 (2002-01-04)	PL 115-52, 131 Stat. 1005, 1047 (2017-08-18)	N
1004	394	Scientific review groups	PL 101-635, 104 Stat. 4583, 4584 (1990-11-28)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	N
1005	395	Loan repayment program	PL 103-43, 107 Stat. 122, 210 (1993-06-10)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	N
1006	396	Practice of medicine	PL 105-115, 111 Stat. 2296, 2348 (1997-11-21)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	Y

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FFDCA §	21 U.S.C. §	Section Title	Added by	Last Amended	Excerpt Incl. in Supp? (Y/N)
1007	397	Contracts for expert review	PL 105-115, 111 Stat. 2296, 2377 (1997-11-21)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	N
1008	398	Notices to States regarding imported food	PL 107-188, 116 Stat. 594, 673 (2002-06-12)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	N
1009	399	Grants to enhance food safety	PL 107-188, 116 Stat. 594, 673 (2002-06-12)	PL 111-353, 124 Stat. 3885, 3948 (2011-01-04)	N
1010	399a	Office of the Chief Scientist	PL 110-85, 121 Stat. 823, 898 (2007-09-27)	PL 111-31, 123 Stat. 1776, 1784 (2009-06-22)	N
1011	399b	Office of Women's Health	PL 111-148, 124 Stat. 119, 536 (2010-03-23)	Not amended	N
1012	399c	Improving the training of State, local, territorial, and tribal food safety officials	PL 111-353, 124 Stat. 3885, 3945 (2011-01-04)	PL 114-255, 130 Stat. 1033, 1137 (2016-12-13)	N
1013	399d	Employee protections	PL 111-353, 124 Stat. 3885, 3968 (2011-01-04)	PL 114-255, 130 Stat. 1033, 1137 (2016-12-13)	N
N/A	399e	Nanotechnology	PL 112-144, 126 Stat. 993, 1116 (2012-07-09)	Not amended	N
N/A	399f	Ensuring adequate information regarding pharmaceuticals for all populations, particularly underrepresented sub-populations, including racial subgroups	PL 112-144, 126 Stat. 993, 1125 (2012-07-09)	Not amended	N
1014	399g	Food and Drug Administration Intercenter Institutes	PL 114-255, 130 Stat. 1033, 1136 (2016-12-13)	Not amended	N
N/A	399h	National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing	PL 117-328, 136 Stat. 4459, 5815 (2022-12-29)	Not amended	N
N/A	399i	Food and Drug Administration Working Capital Fund	PL 115-141, 132 Stat. 348, 387 (2018-03-28)	Not amended	N

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Chart 4: The 50 Titles of the Code of Federal Regulations

The 50 Titles of the Code of Federal Regulations		
Title 1. General Provisions	Title 19. Customs Duties	Title 37. Patents, Trademarks, and Copyrights
Title 2. Grants and Agreements	Title 20. Employees' Benefits	Title 38. Pensions, Bonuses, and Veterans' Relief
Title 3. The President	**Title 21. Food and Drugs**	Title 39. Postal Service
Title 4. Accounts	Title 22. Foreign Relations	Title 40. Protection of Environment
Title 5. Administrative Personnel	Title 23. Highways	Title 41. Public Contracts and Property Management
Title 6. Domestic Security	Title 24. Housing and Urban Development	Title 42. Public Health
Title 7. Agriculture	Title 25. Indians	Title 43. Public Lands: Interior
Title 8. Aliens and Nationality	Title 26. Internal Revenue	Title 44. Emergency Management and Assistance
Title 9. Animals and Animal Products	Title 27. Alcohol, Tobacco Products, and Firearms	Title 45. Public Welfare
Title 10. Energy	Title 28. Judicial Administration	Title 46. Shipping
Title 11. Federal Elections	Title 29. Labor	Title 47. Telecommunication
Title 12. Banks and Banking	Title 30. Mineral Resources	Title 48. Federal Acquisition Regulations System
Title 13. Business Credit and Assistance	Title 31. Money and Finance: Treasury	Title 49. Transportation
Title 14. Aeronautics and Space	Title 32. National Defense	Title 50. Wildlife and Fisheries
Title 15. Commerce and Foreign Trade	Title 33. Navigation and Navigable Waters	
Title 16. Commercial Practices	Title 34. Education	
Title 17. Commodity and Securities Exchanges	Title 35. [Reserved]	
Title 18. Conservation of Power and Water Resources	Title 36. Parks, Forests, and Public Property	

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Chart 5: The Structure of the Code of Federal Regulations, Title 21—Food and Drugs

Structure of Code of Federal Regulations, Title 21
1–1299: Chapter I—Food and Drug Administration, Department of Health and Human Services
1–99: Subchapter A—*General* (Vol. 1)
100–199: Subchapter B—*Food for Human Consumption* 100–169: *[food generally]* (Vol. 2) 170–199: *[substances added to food; dietary supplements]* (Vol. 3)
200–299: Subchapter C—*Drugs: General* (Vol. 4)
300–499: Subchapter D—*Drugs for Human Use* (Vol. 5)
500–599: Subchapter E—*Animal Drugs, Feeds, and Related Products* (Vol. 6)
600–680: Subchapter F—*Biologics* (Vol. 7)
700–799: Subchapter G—*Cosmetics* (Vol 7, cont'd)
800–898: Subchapter H—*Medical Devices* (Vol. 8)
900: Subchapter I—*Mammography Quality Standards Act* (Vol 8, cont'd)
1000–1040: Subchapter J—*Radiological Health* (Vol 8, cont'd)
1100–1150: Subchapter K—*Tobacco Products* (Vol 8, cont'd)
1210–1299: Subchapter L—*Regulations Under Certain Other Acts Administered by the Food & Drug Admin.* (Vol 8, cont'd)
1300–1399: Chapter II—Drug Enforcement Administration, Department of Justice (Vol. 9)
1400–1499: Chapter III—Office of National Drug Control Policy (Vol 9, cont'd)

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Chart 6: List of all "Parts" of the Code of Federal Regulations, Title 21—Food and Drugs

21 C.F.R. Part	21 C.F.R. § Range	Section Title	Excerpt Included in Supp? (Y//N)
		1–1299: Chapter I—FDA (HHS)	
		1–99: SUBCHAPTER A—GENERAL (VOL. 1)	
1	1.1 to 1.1465	General enforcement regulations	N
2	2.5 to 2.125	General administrative rulings and decisions	N
3	3.1 to 3.10	Product jurisdiction	Y
4	4.1 to 4.105	Regulation of combination products	Y
5	5.1100 to 5.1110	Organization	N
7	7.1 to 7.87	Enforcement policy	N
10	10.1 to 10.206	Administrative practices and procedures	Y
11	11.1 to 11.300	Electronic records; electronic signatures	N
12	12.1 to 12.159	Formal evidentiary public hearing	N
13	13.1 to 13.50	Public hearing before a public board of inquiry	N
14	14.1 to 14.174	Public hearing before a public advisory committee	N
15	15.1 to 15.45	Public hearing before the commissioner	N
16	16.1 to 16.120	Regulatory hearing before the food and drug administration	N
17	17.1 to 17.54	Civil money penalties hearings	N
19	19.1 to 19.55	Standards of conduct and conflicts of interest	N
20	20.1 to 20.120	Public information	N

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21	21.1 to 21.75	Protection of privacy	N
25	25.1 to 25.60	Environmental impact considerations	N
26	26.0 to 26.81	Mutual recognition of pharmaceutical good manufacturing practice reports, medical device quality system audit reports, and certain medical device product evaluation reports: United States and the European community	N
50	50.1 to 50.56	Protection of human subjects	Y
54	54.1 to 54.6	Financial disclosure by clinical investigators	N
56	56.101 to 56.124	Institutional review boards	Y
58	58.1 to 58.219	Good laboratory practice for nonclinical laboratory studies	Y
60	60.1 to 60.46	Patent term restoration	N
70	70.3 to 70.55	Color additives	Y
71	71.1 to 71.37	Color additive petitions	Y
73	73.1 to 73.3129	Listing of color additives exempt from certification	N
74	74.101 to 74.3710	Listing of color additives subject to certification	N
80	80.10 to 80.39	Color additive certification	N
81	81.1 to 81.30	General specifications and general restrictions for provisional color additives for use in foods, drugs, and cosmetics	N
82	82.3 to 82.2707a	Listing of certified provisionally listed colors and specifications	N
83–98	N/A	[Reserved]	N
99	99.1 to 99.501	Dissemination of information on unapproved/new uses for marketed drugs, biologics, and devices	N
		100–199: SUBCHAPTER B – FOOD FOR HUMAN CONSUMPTION	
		100–169: [FOOD GENERALLY] (VOL. 2)	
100	100.1 to 100.155	General	N
101	101.1 to 101.108	Food labeling	Y
102	102.5 to 102.57	Common or usual name for nonstandardized foods	Y

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104	104.5 to 104.47	Nutritional quality guidelines for foods	N
105	105.3 to 105.66	Foods for special dietary use	Y
106	106.1 to 106.160	Infant formula requirements pertaining to current good manufacturing practice, quality control procedures, quality factors, records and reports, and notifications	N
107	107.1 to 107.280	Infant formula	N
108	108.3 to 108.35	Emergency permit control	N
109	109.3 to 109.30	Unavoidable contaminants in food for human consumption and food-packaging material	N
110	110.3 to 110.110	Current good manufacturing practice in manufacturing, packing, or holding human food *[currently in phase-out; see 83 FR 46104 (2018-09-12)]*	N
111	111.1 to 111.610	Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements	N
112	112.1 to 112.213	Standards for the growing, harvesting, packing, and holding of produce for human consumption	N
113	113.3 to 113.100	Thermally processed low-acid foods packaged in hermetically sealed containers	N
114	114.3 to 114.100	Acidified foods	N
115	115.50	Shell eggs	N
117	117.1 to 117.475	Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food	Y
118	118.1 to 118.12	Production, storage, and transportation of shell eggs	N
119	119.1	Dietary supplements that present a significant or unreasonable risk	N
120	120.1 to 120.25	Hazard analysis and critical control point (HACCP) systems	N
121	121.1 to 121.401	Mitigation strategies to protect food against intentional adulteration	N
123	123.3 to 123.28	Fish and fishery products	N
129	129.1 to 129.80	Processing and bottling of bottled drinking water	N
130	130.3 to 130.20	Food standards: general	N
131	131.3 to 131.200	Milk and cream	N
133	133.3 to 133.196	Cheeses and related cheese products	N

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135	135.3 to 135.160	Frozen desserts	N
136	136.3 to 136.180	Bakery products	N
137	137.105 to 137.350	Cereal flours and related products	N
139	139.110 to 139.180	Macaroni and noodle products	N
145	145.3 to 145.190	Canned fruits	N
146	146.3 to 146.187	Canned fruit juices	N
150	150.110 to 150.160	Fruit butters, jellies, preserves, and related products	N
155	155.3 to 155.201	Canned vegetables	N
156	156.3 to 156.145	Vegetable juices	N
158	158.3 to 158.170	Frozen vegetables	N
160	160.100 to 160.190	Eggs and egg products	N
161	161.30 to 161.190	Fish and shellfish	N
163	163.5 to 163.155	Cacao products	N
164	164.110 to 164.150	Tree nut and peanut products	N
165	165.3 to 165.110	Beverages	N
166	166.40 to 166.110	Margarine	N
168	168.110 to 168.180	Sweeteners and table sirups	N
169	169.3 to 169.182	Food dressings and flavorings	N
		170–199: [SUBSTANCES ADDED TO FOOD; DIETARY SUPPLEMENTS] (VOL. 3)	
170	170.3 to 170.285	Food additives	N
171	171.1 to 171.130	Food additive petitions	N
172	172.5 to 172.898	Food additives permitted for direct addition to food for human consumption	N
173	173.5 to 173.405	Secondary direct food additives permitted in food for human consumption	N
174	174.5 to 174.6	Indirect food additives: general	N
175	175.105 to 175.390	Indirect food additives: adhesives and components of coatings	N

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176	176.110 to 176.350	Indirect food additives: paper and paperboard components	N
177	177.1010 to 177.2910	Indirect food additives: polymers	N
178	178.1005 to 178.3950	Indirect food additives: adjuvants, production aids, and sanitizers	N
179	179.21 to 179.45	Irradiation in the production, processing and handling of food	N
180	180.1 to 180.37	Food additives permitted in food or in contact with food on an interim basis pending additional study	N
181	181.1 to 181.34	Prior-sanctioned food ingredients	N
182	182.1 to 182.8997	Substances generally recognized as safe	N
184	184.1 to 184.1985	Direct food substances affirmed as generally recognized as safe	N
186	186.1 to 186.1839	Indirect food substances affirmed as generally recognized as safe	N
189	189.1 to 189.301	Substances prohibited from use in human food	N
190	190.6	Dietary supplements	Y
191–199	N/A	[Reserved]	N
		200–299: SUBCHAPTER C—DRUGS: GENERAL (VOL. 4)	
200	200.5 to 200.200	General	N
201	201.1 to 201.328	Labeling	N
202	202.1	Prescription drug advertising	N
203	203.1 to 203.70	Prescription drug marketing	N
205	205.1 to 205.50	Guidelines for state licensing of wholesale prescription drug distributors	N
206	206.1 to 206.10	Imprinting of solid oral dosage form drug products for human use	N
207	207.1 to 207.81	Requirements for foreign and domestic establishment registration and listing for human drugs, including drugs that are regulated under a biologics license application, and animal drugs, and the national drug code	N
208	208.1 to 208.26	Medication guides for prescription drug products	N
209	209.1 to 209.11	Requirement for authorized dispensers and pharmacies to distribute a side effects statement	N

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210	210.1 to 210.3	Current good manufacturing practice in manufacturing, processing, packing, or holding of drugs; general	N
211	211.1 to 211.208	Current good manufacturing practice for finished pharmaceuticals	N
212	212.1 to 212.110	Current good manufacturing practice for positron emission tomography drugs	N
216	216.23 to 216.24	Human drug compounding	N
225	225.1 to 225.202	Current good manufacturing practice for medicated feeds	N
226	226.1 to 226.115	Current good manufacturing practice for type a medicated articles	N
250	250.11 to 250.250	Special requirements for specific human drugs	N
251	251.1 to 251.21	Section 804 importation program	N
290	290.1 to 290.10	Controlled drugs	N
299	299.3 to 299.5	Drugs; official names and established names	N
		300–499: SUBCHAPTER D—DRUGS FOR HUMAN USE (VOL. 5)	
300	300.50 to 300.200	General	N
310	310.3 to 310.548	New drugs	Y
312	312.1 to 312.320	Investigational new drug application	N
314	314.1 to 314.650	Applications for FDA approval to market a new drug	Y
315	315.1 to 315.6	Diagnostic radiopharmaceuticals	N
316	316.1 to 316.52	Orphan drugs	N
317	317.1 to 317.2	Qualifying pathogens	N
320	320.1 to 320.63	Bioavailability and bioequivalence requirements	N
328	328.1 to 328.50	Over-the-counter drug products intended for oral ingestion that contain alcohol	N
329	329.100	Nonprescription human drug products subject to section 760 of the federal food, drug, and cosmetic act	N
330	330.1 to 330.15	Over-the-counter (OTC) human drugs which are generally recognized as safe and effective and not misbranded	N
331	331.1 to 331.80	Antacid products for over-the-counter (OTC) human use	N

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332	332.1 to 332.31	Antiflatulent products for over-the-counter human use	N
333	333.101 to 333.350	Topical antimicrobial drug products for over-the-counter human use	N
335	335.1 to 335.50	Antidiarrheal drug products for over-the-counter human use	N
336	336.1 to 336.80	Antiemetic drug products for over-the-counter human use	N
338	338.1 to 338.50	Nighttime sleep-aid drug products for over-the-counter human use	N
340	340.1 to 340.50	Stimulant drug products for over-the-counter human use	N
341	341.1 to 341.90	Cold, cough, allergy, bronchodilator, and antiasthmatic drug products for over-the-counter human use	N
343	343.1 to 343.90	Internal analgesic, antipyretic, and antirheumatic drug products for over-the-counter human use	N
344	344.1 to 344.52	Topical otic drug products for over-the-counter human use	N
346	346.1 to 346.52	Anorectal drug products for over-the-counter human use	N
347	347.1 to 347.60	Skin protectant drug products for over-the-counter human use	N
348	348.1 to 348.50	External analgesic drug products for over-the-counter human use	N
349	349.1 to 349.80	Ophthalmic drug products for over-the-counter human use	N
350	350.1 to 350.60	Antiperspirant drug products for over-the-counter human use	N
352	352.1 to 352.77	Sunscreen drug products for over-the-counter human use *[stayed indefinitely by 68 FR 33381 (2004-06-03)]*	N
355	355.1 to 355.70	Anticaries drug products for over-the-counter human use	N
357	357.101 to 357.850	Miscellaneous internal drug products for over-the-counter human use	N
358	358.101 to 358.760	Miscellaneous external drug products for over-the-counter human use	N
361	361.1	Prescription drugs for human use generally recognized as safe and effective and not misbranded: drugs used in research	N
369	369.1 to 369.21	Interpretative statements re warnings on drugs and devices for over-the-counter sale	N
370–499	N/A	[Reserved]	N
500–599: SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS (VOL. 6)			

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500	500.23 to 500.1410	General	N
501	501.1 to 501.110	Animal food labeling	N
502	502.5 to 502.19	Common or usual names for nonstandardized animal foods	N
507	507.1 to 507.215	Current good manufacturing practice, hazard analysis, and risk-based preventive controls for food for animals	N
509	509.3 to 509.30	Unavoidable contaminants in animal food and food-packaging material	N
510	510.3 to 510.600	New animal drugs	Y
511	511.1 to 511.3	New animal drugs for investigational use	N
514	514.1 to 514.235	New animal drug applications	Y
515	515.10 to 515.40	Medicated feed mill license	N
516	516.1 to 516.2980	New animal drugs for minor use and minor species	N
520	520.23 to 520.2645	Oral dosage form new animal drugs	N
522	522.23 to 522.2690	Implantation or injectable dosage form new animal drugs	N
524	524.86 to 524.2620	Ophthalmic and topical dosage form new animal drugs	N
526	526.88 to 526.1810	Intramammary dosage form new animal drugs	N
528	528.1080 to 528.2010	New animal drugs in genetically engineered animals	N
529	529.56 to 529.2620	Certain other dosage form new animal drugs	N
530	530.1 to 530.41	Extralabel drug use in animals	Y
556	556.1 to 556.770	Tolerances for residues of new animal drugs in food	N
558	558.3 to 558.680	New animal drugs for use in animal feeds	N
564	N/A	[Reserved]	N
570	570.3 to 570.280	Food additives	N
571	571.1 to 571.130	Food additive petitions	N
573	573.120 to 573.1020	Food additives permitted in feed and drinking water of animals	N
579	579.12 to 579.40	Irradiation in the production, processing, and handling of animal feed and pet food	N
582	582.1 to 582.7724	Substances generally recognized as safe	N

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584	584.200 to 584.725	Food substances affirmed as generally recognized as safe in feed and drinking water of animals	N
589	589.1 to 589.2001	Substances prohibited from use in animal food or feed	N
590–599	N/A	[Reserved]	N
		600–699: SUBCHAPTER F—BIOLOGICS (VOL. 7)	
600	600.2 to 600.90	Biological products: general	N
601	601.2 to 601.95	Licensing	Y
606	606.3 to 606.171	Current good manufacturing practice for blood and blood components	N
607	607.1 to 607.80	Establishment registration and product listing for manufacturers of human blood and blood products and licensed devices	N
610	610.1 to 610.68	General biological products standards	Y
630	630.1 to 630.40	Requirements for blood and blood components intended for transfusion or for further manufacturing use	N
640	640.1 to 640.130	Additional standards for human blood and blood products	N
660	660.1 to 660.55	Additional standards for diagnostic substances for laboratory tests	N
680	680.1 to 680.3	Additional standards for miscellaneous products	N
		700–799: SUBCHAPTER G—COSMETICS (VOL. 7, CONT'D)	
700	700.3 to 700.35	General	N
701	701.1 to 701.30	Cosmetic labeling	Y
710	710.1 to 710.9	Voluntary registration of cosmetic product establishments	Y
720	720.1 to 720.9	Voluntary filing of cosmetic product ingredient composition statements	Y
740	740.1 to 740.19	Cosmetic product warning statements	Y
741–799	N/A	[Reserved]	N
		800–898: SUBCHAPTER H—MEDICAL DEVICES (VOL. 8)	
800	800.10 to 800.75	General	N

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801	801.1 to 801.437	Labeling	N
803	803.1 to 803.58	Medical device reporting	N
806	806.1 to 806.40	Medical devices; reports of corrections and removals	N
807	807.3 to 807.100	Establishment registration and device listing for manufacturers and initial importers of devices	Y
808	808.1 to 808.101	Exemptions from federal preemption of state and local medical device requirements	Y
809	809.3 to 809.40	In vitro diagnostic products for human use	N
810	810.1 to 810.18	Medical device recall authority	N
812	812.1 to 812.150	Investigational device exemptions	N
813	N/A	[Reserved]	N
814	814.1 to 814.126	Premarket approval of medical devices	Y
820	820.1 to 820.250	Quality system regulation	N
821	821.1 to 821.60	Medical device tracking requirements	N
822	822.1 to 822.38	Postmarket surveillance	N
830	830.3 to 830.360	Unique device identification	N
860	860.1 to 860.260	Medical device classification procedures	Y
861	861.1 to 861.38	Procedures for performance standards development	N
862	862.1 to 862.3950	Clinical chemistry and clinical toxicology devices	N
864	864.1 to 864.9900	Hematology and pathology devices	N
866	866.1 to 866.6080	Immunology and microbiology devices	N
868	868.1 to 868.6885	Anesthesiology devices	Y
870	870.1 to 870.5925	Cardiovascular devices	Y
872	872.1 to 872.6890	Dental devices	Y
874	874.1 to 874.5900	Ear, nose, and throat devices	N
876	876.1 to 876.5990	Gastroenterology-urology devices	N
878	878.1 to 878.5910	General and plastic surgery devices	Y

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880	880.1 to 880.6992	General hospital and personal use devices	Y
882	882.1 to 882.5970	Neurological devices	N
884	884.1 to 884.6200	Obstetrical and gynecological devices	N
886	886.1 to 886.5933	Ophthalmic devices	N
888	888.1 to 888.5980	Orthopedic devices	N
890	890.1 to 890.5975	Physical medicine devices	Y
892	892.1 to 892.6500	Radiology devices	Y
895	895.1 to 895.105	Banned devices	Y
898	898.11 to 898.14	Performance standard for electrode lead wires and patient cables	Y
		900: SUBCHAPTER I—MAMMOGRAPHY QUALITY STANDARDS ACT (VOL 8, CONT'D)	
900	900.1 to 900.25	Mammography	N
		1000–1040: SUBCHAPTER J—RADIOLOGICAL HEALTH (VOL 8, CONT'D)	
1000	1000.1 to 1000.15	General	N
1002	1002.1 to 1002.51	Records and reports	N
1003	1003.1 to 1003.31	Notification of defects or failure to comply	N
1004	1004.1 to 1004.6	Repurchase, repairs, or replacement of electronic products	N
1005	1005.1 to 1005.25	Importation of electronic products	N
1010	1010.1 to 1010.20	Performance standards for electronic products: general	N
1020	1020.10 to 1020.40	Performance standards for ionizing radiation emitting products	N
1030	1030.10	Performance standards for microwave and radio frequency emitting products	N
1040	1040.10 to 1040.30	Performance standards for light-emitting products	N
		1100–1150: SUBCHAPTER K—TOBACCO PRODUCTS (VOL 8, CONT'D)	
1100	1100.1 to 1100.204	Tobacco products subject to FDA authority	Y
1105	1105.10	General	N
1107	1107.1 to 1107.62	Exemption Requests and Substantial Equivalence Reports	N

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1114	1114.1-1114.49	Premarket Tobacco Product Applications	N
1140	1140.1 to 1140.34	Cigarettes, smokeless tobacco, and covered tobacco products	Y
1141	1141.1 to 1141.12	Cigarette package and advertising warnings	N
1143	1143.1 to 1143.13	Minimum required warning statements	N
1150	1150.1 to 1150.17	User fees	N
		1210–1299: SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION (VOL 8, CONT'D)	
1210	1210.1 to 1210.31	Regulations under the federal import milk act	N
1230	1230.2 to 1230.49	Regulations under the federal caustic poison act	N
1240	1240.3 to 1240.95	Control of communicable diseases	N
1250	1250.3 to 1250.96	Interstate conveyance sanitation	N
1251–1269	N/A	[Reserved]	N
1270	1270.1 to 1270.43	Human tissue intended for transplantation *[revoked by 87 FR 2045 (2022-01-13)]*	Y
1271	1271.1 to 1271.440	Human cells, tissues, and cellular and tissue-based products	Y
1272–1299	N/A	[Reserved]	N
		1300–1399: CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE (VOL 9)	
1300	1300.01 to 1300.05	Definitions	N
1301	1301.01 to 1301.93	Registration of manufacturers, distributors, and dispensers of controlled substances	N
1302	1302.01 to 1302.08	Labeling and packaging requirements for controlled substances	N
1303	1303.01 to 1303.37	Quotas	N
1304	1304.01 to 1304.55	Records and reports of registrants	N
1305	1305.01 to 1305.29	Orders for schedule I and II controlled substances	N
1306	1306.01 to 1306.27	Prescriptions	N
1307	1307.01 to 1307.41	Miscellaneous	N
1308	1308.01 to 1308.50	Schedules of controlled substances	N

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1309	1309.01 to 1309.73	Registration of manufacturers, distributors, importers and exporters of list I chemicals	N
1310	1310.01 to 1310.21	Records and reports of listed chemicals and certain machines; importation and exportation of certain machines	N
1311	1311.01 to 1311.305	Requirements for electronic orders and prescriptions	N
1312	1312.01 to 1312.47	Importation and exportation of controlled substances	N
1313	1313.01 to 1313.57	Importation and exportation of list I and list II chemicals	N
1314	1314.01 to 1314.155	Retail sale of scheduled listed chemical products	N
1315	1315.01 to 1315.62	Importation and production quotas for ephedrine, pseudoephedrine, and phenylpropanolamine	N
1316	1316.01 to 1316.68	Administrative functions, practices, and procedures	N
1317	1317.01 to 1317.95	Disposal	N
1318	1318.01 to 1318.07	Controls to satisfy the requirements of the act applicable to the manufacturing of marihuana	N
1321	1321.01	DEA mailing addresses	N
1322–1399	N/A	[Reserved]	N/A
		1400–1499: CHAPTER III—OFFICE OF NATIONAL DRUG CONTROL POLICY (VOL 9, CONT'D)	
1400	N/A	[Reserved]	N
1401	1401.1 to 1401.24	Public availability of information	N
1402	1402.1 to 1402.7	Mandatory declassification review	N
1403–1499	N/A	[Reserved]	N

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Chart 7: C.F.R. "Sections" Excerpted in this Supplement

Last-amended dates are listed for individual C.F.R. sections, but not full C.F.R. Parts.

C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
Title 9. Animals and Animal Products				
9	101	N/A	Definitions	
9	101	101.2	Administrative terminology	83 FR 22835 (2018-05-17)
9	102	N/A	Licenses for biological products	
9	102	102.1	Licenses issued by the Administrator	60 FR 48021 (1995-09-18)
9	102	102.2	Licenses required	61 FR 52873 (1996-10-09)
Title 21. Food and Drugs				
21	3	N/A	Product jurisdiction	
21	3	3.1	Purpose	68 FR 37077 (2003-06-23)
21	3	3.2	Definitions	70 FR 49861 (2005-08-25)
21	3	3.3	Scope	56 FR 58756 (1991-11-21)
21	3	3.5	Procedures for identifying the designated agency component	88 FR 45064 (2023-07-14)

* Last amended dates reflect the last change to the text of the relevant CFR section. This includes minor technical changes, including updates to the title or address of an FDA office. It does not, however, include updates that make changes only to the statutory authority listed for the relevant CFR section. For consistency, the page of the *Federal Register* cited is the first page following the preamble of the cited document. This often (but not always) matches the most recent *Federal Register* page cited as the "SOURCE" in the listing for the affected CFR section on Westlaw.

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	4	N/A	Regulation of combination products	
21	4	4.1	What is the scope of this subpart?	78 FR 4321 (2013-01-22)
21	4	4.2	How does the FDA define key terms and phrases in this subpart?	89 FR 7522 (2024-02-02)
21	4	4.3	What current good manufacturing practice requirements apply to my combination product?	78 FR 4321 (2013-01-22)
21	4	4.100	What is the scope of this subpart?	81 FR 92624 (2016-12-20)
21	4	4.102	What reports must you submit to FDA for your combination product or constituent part?	81 FR 92624 (2016-12-20)
21	10	N/A	Administrative practices and procedure	
21	10	10.115	Good guidance practices	83 FR 13416 (2018-03-29)
21	50	N/A	Protection of human subjects	
21	50	50.1	Scope	66 FR 20597 (2001-04-24)
21	50	50.3	Definitions	78 FR 12950 (2013-02-26)
21	50	50.20	General requirements for informed consent	88 FR 88248 (2023-12-21)
21	50	50.22	Exception from informed consent requirements for minimal risk clinical investigations	88 FR 88248 (2023-12-21)
21	50	50.23	Exception from general requirements	76 FR 36993 (2011-06-24)
21	50	50.24	Exception from informed consent requirement for emergency research	61 FR 51528 (1996-10-02)
21	50	50.27	Documentation of informed consent	61 FR 57280 (1996-11-05)
21	50	50.50	IRB duties	66 FR 20597 (2001-04-24)
21	56	N/A	Institutional review boards	
21	56	56.101	Scope	66 FR 20597 (2001-04-24)
21	56	56.102	Definitions	74 FR 2368 (2009-01-15)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	56	56.103	Circumstances in which IRB review is required	46 FR 14340 (1981-02-27)
21	56	56.104	Exemptions from IRB requirement	56 FR 28028 (1991-06-18)
21	56	56.105	Waiver of IRB requirement	46 FR 8975 (1981-01-27)
21	56	56.106	Registration	78 FR 16401 (2013-03-15)
21	56	56.107	IRB membership	78 FR 16401 (2013-03-15)
21	56	56.109	IRB review of research	78 FR 12952 (2013-02-26)
21	56	56.111	Criteria for IRB approval of research	66 FR 20597 (2001-04-24)
21	56	56.112	Review by institution	46 FR 8975 (1981-01-27)
21	56	56.114	Cooperative research	46 FR 8975 (1981-01-27)
21	58	N/A	Good laboratory practices for nonclinical laboratory studies	
21	58	58.1	Scope	64 FR 398 (1999-01-05)
21	58	58.10	Applicability to studies performed under grants and contracts	43 FR 60013 (1978-12-22)
21	58	58.15	Inspection of a testing facility	43 FR 60013 (1978-12-22)
21	58	58.29	Personnel	43 FR 60013 (1978-12-22)
21	58	58.31	Testing facility management	52 FR 33779 (1987-09-04)
21	58	58.41	General	52 FR 33779 (1987-09-04)
21	58	58.81	Standard operating procedures	52 FR 33779 (1987-09-04)
21	58	58.105	Test and control article characterization	67 FR 9585 (2002-03-04)
21	58	58.120	Protocol	67 FR 9585 (2002-03-04)
21	58	58.185	Reporting of nonclinical laboratory study results	52 FR 33779 (1987-09-04)
21	70	N/A	Color additives	
21	70	70.3	Definitions	61 FR 14478 (1996-04-02)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	70	70.40	Safety factors to be considered	42 FR 15553 (1977-03-22)
21	70	70.42	Criteria for evaluating the safety of color additives	42 FR 15553 (1977-03-22)
21	70	70.50	Application of the cancer clause of section 721 of the act	52 FR 49586 (1987-12-31)
21	71	N/A	Color additive petitions	
21	71	71.1	Petitions	81 FR 49895 (2016-07-29)
21	71	71.2	Notice of filing of petition	64 FR 398 (1999-01-05)
21	71	71.37	Exemption of color additives for investigational use	42 FR 15553 (1977-03-22)
21	101	N/A	Food labeling	
21	101	101.1	Principal display panel of package form food	42 FR 14302 (1977-03-15)
21	101	101.2	Information panel of package form food	81 FR 59131 (2016-08-29)
21	101	101.3	Identity labeling of food in packaged form	62 FR 49847 (1997-09-23)
21	101	101.4	Food; designation of ingredients	88 FR 17716 (2023-03-24)
21	101	101.9	Nutrition labeling of food	88 FR 33550 (2023-05-24)
21	101	101.14	Health claims: general requirements	66 FR 17358 (2001-03-30)
21	101	101.15	Food; prominence of required statements	42 FR 14302 (1977-03-15)
21	101	101.18	Misbranding of food	42 FR 14302 (1977-03-15)
21	101	101.93	Certain types of statements for dietary supplements	88 FR 17716 (2023-03-24)
21	102	N/A	Common or usual name for nonstandardized foods	
21	102	102.5	General Principles	42 FR 14302 (1977-03-15)
21	105	N/A	Foods for special dietary use	
21	105	105.3	Definitions and interpretations	44 FR 49665 (1979-08-24)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	117	N/A	Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food	
21	117	117.1	Applicability and status	81 FR 3715 (2016-01-22)
21	190	N/A	Dietary supplements	
21	190	190.6	Requirement for premarket notification	88 FR 17716 (2023-03-24)
21	310	N/A	New drugs	
21	310	310.6	Applicability of "new drug" or safety or effectiveness findings in drug efficacy study implementation notices and notices of opportunity for hearing to identical, related, and similar drug products	74 FR 13112 (2009-03-26)
21	310	310.100	New drug status opinions; statement of policy	39 FR 11680 (1974-03-29)
21	314	N/A	Applications for FDA approval to market a new drug	
21	314	314.70	Supplements and other changes to an approved NDA	81 FR 69636 (2016-10-06)
21	314	314.125	Refusal to approve an NDA	81 FR 69636 (2016-10-06)
21	314	314.126	Adequate and well-controlled studies	67 FR 9584 (2002-03-04)
21	314	314.600	Scope	67 FR 37995 (2002-05-31)
21	314	314.610	Approval based on evidence of effectiveness from studies in animals	67 FR 37995 (2002-05-31)
21	314	314.640	Promotional materials	67 FR 37995 (2002-05-31)
21	314	314.650	Termination of requirements	67 FR 37995 (2002-05-31)
21	510	N/A	New animal drugs	
21	510	510.3	Definitions and interpretations	72 FR 41017 (2007-07-26)
21	514	N/A	New animal drug applications	
21	514	514.4	Substantial evidence	64 FR 40756 (1999-07-28)
21	514	514.111	Refusal to approve an application	81 FR 60221 (2016-08-31)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	514	514.117	Adequate and well-controlled studies	63 FR 10770 (1998-03-05)
21	530	N/A	Extralabel drug use in animals	
21	530	530.1	Scope	61 FR 57743 (1996-11-07)
21	530	530.2	Purpose	61 FR 57743 (1996-11-07)
21	530	530.3	Definitions	61 FR 57743 (1996-11-07)
21	530	530.4	Advertising and promotions	61 FR 57743 (1996-11-07)
21	530	530.5	Veterinary records	61 FR 57743 (1996-11-07)
21	530	530.10	Provision permitting extralabel use of animal drugs	61 FR 57743 (1996-11-07)
21	530	530.21	Prohibitions on food-producing animals	61 FR 57743 (1996-11-07)
21	600	N/A	General	
21	600	600.3	Definitions	85 FR 10063 (2020-02-21)
21	601	N/A	Licensing	
21	601	601.2	Applications for biologics licenses; procedures for filing	89 FR 9756 (2024-02-12)
21	601	601.4	Issuance and denial of license	70 FR 14980 (2005-03-24)
21	601	601.90	Scope	67 FR 37995 (2002-05-31)
21	601	601.91	Approval based on evidence of effectiveness from studies in animals	67 FR 37995 (2002-05-31)
21	610	N/A	General biological product standards	
21	610	610.1	Tests prior to release required for each lot	38 FR 32048 (1973-11-20)
21	610	610.10	Potency	38 FR 32048 (1973-11-20)
21	610	610.12	Sterility	77 FR 26174 (2012-05-03)
21	610	610.13	Purity	70 FR 14980 (2005-03-24)
21	700	N/A	General	

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	700	700.3	Definitions	46 FR 38073 (1981-07-24)
21	700	700.25	Tamper-resistant packaging requirements for cosmetic products	48 FR 37624 (1983-08-19)
21	700	700.35	Cosmetics containing sunscreen ingredients	64 FR 27687 (1999-05-21)
21	701	N/A	Cosmetic labeling	
21	701	701.1	Misbranding	39 FR 10054 (1974-03-15)
21	701	701.3	Designation of ingredients	81 FR 49895 (2016-07-29)
21	701	701.11	Identity labeling	39 FR 10054 (1974-03-15)
21	710	N/A	Voluntary registration of cosmetic product establishments	
21	710	710.1	Who should register	39 FR 10054 (1974-03-15)
21	710	710.9	Exemptions	39 FR 10054 (1974-03-15)
21	720	N/A	Voluntary filing of cosmetic product ingredient composition statements	
21	720	720.1	Who should file	57 FR 3129 (1992-01-28)
21	720	720.4	Information requested about cosmetic products	57 FR 3129 (1992-01-28)
21	720	720.9	Misbranding by reference to filing or to statement number	57 FR 3129 (1992-01-28)
21	740	N/A	Cosmetic product warning statements	
21	740	740.1	Establishment of warning statements	42 FR 15673 (1977-03-22)
21	740	740.10	Labeling of cosmetic products for which adequate substantiation of safety has not been obtained	40FR 8917 (1975-03-03)
21	740	740.17	Foaming detergent bath products	51 FR 20475 (1986-06-05)
21	807	N/A	Establishment registration and device listing for manufacturers and initial importers of devices	
21	807	807.81	When a premarket notification submission is required	89 FR 18792 (2024-03-15)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	807	807.85	Exemption from premarket notification	81 FR 70340 (2016-10-12)
21	807	807.87	Information required in a premarket notification submission	89 FR 18792 (2024-03-15)
21	807	807.90	Format of a premarket notification submission	84 FR 68339 (2019-12-16)
21	807	807.92	Content and format of a 510(k) summary	59 FR 64295 (1994-12-14)
21	807	807.97	Misbranding by reference to premarket notification	42 FR 42526 (1977-08-23)
21	807	807.100	FDA action on a premarket notification	63 FR 5250 (1998-02-02)
21	808	N/A	Exemptions from federal preemption of state and local medical device requirements	
21	808	808.1	Scope	87 FR 50748 (2022-08-22)
21	808	808.3	Definitions	87 FR 50748 (2022-08-22)
21	808	808.5	Advisory opinions	87 FR 50748 (2022-08-22)
21	814	N/A	Premarket approval of medical devices	
21	814	814.1	Scope	79 FR 1740 (2014-01-10)
21	860	N/A	Medical device classification procedures	
21	860	860.1	Scope	86 FR 54846 (2021-10-05)
21	860	860.3	Definitions	86 FR 54846 (2021-10-05)
21	860	860.7	Determination of safety and effectiveness	83 FR 64454 (2018-12-17)
21	860	860.84	Classification procedures for “preamendments devices”	83 FR 64454 (2018-12-17)
21	860	860.120	General	83 FR 64454 (2018-12-17)
21	868	N/A	Anesthesiology devices	
21	868	868.5895	Continuous ventilator	47 FR 31142 (1982-07-16)
21	868	868.5905	Noncontinuous ventilator (IPPB)	47 FR 31142 (1982-07-16)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	868	868.5915	Manual emergency ventilator	47 FR 31142 (1982-07-16)
21	868	868.5925	Powered emergency ventilator	47 FR 31142 (1982-07-16)
21	868	868.5975	Ventilator tubing	66 FR 38787 (2001-07-25)
21	870	N/A	Cardiology devices	
21	870	870.1200	Diagnostic intravascular catheter	45 FR 7907 (1980-02-05)
21	870	870.1875	Stethoscope	84 FR 71796 (2019-12-30)
21	870	870.3610	Implantable pacemaker pulse generator	77 FR 37576 (2012-06-22)
21	870	870.3620	Pacemaker lead adapter	66 FR 18542 (2001-04-10)
21	872	N/A	Dental devices	
21	872	872.6855	Manual toothbrush	66 FR 38787 (2001-07-25)
21	872	872.6865	Powered toothbrush	66 FR 38787 (2001-07-25)
21	878	N/A	General and plastic surgery devices	
21	878	878.3530	Silicone inflatable breast prothesis	64 FR 45161 (1999-08-19)
21	878	878.3540	Silicone gel-filled breast prothesis	56 FR 14627 (1991-04-10)
21	878	878.4040	Surgical apparel	83 FR 22848 (2018-05-17)
21	880	N/A	General hospital and personal use devices	
21	880	880.6260	Filtering facepiece respirator for use by the general public in public health medical emergencies	72 FR 36362 (2007-07-03)
21	890	N/A	Physical medicine devices	
21	890	890.3075	Cane	66 FR 38787 (2001-07-25)
21	890	890.3150	Crutch	66 FR 38787 (2001-07-25)
21	890	890.3850	Mechanical wheelchair	48 FR 53046 (1983-11-23)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	890	890.3860	Powered wheelchair	48 FR 53046 (1983-11-23)
21	892	N/A	Radiology devices	
21	892	892.1000	Magnetic resonance diagnostic device	84 FR 71796 (2019-12-30)
21	895	N/A	Banned devices	
21	895	895.1	Scope	44 FR 58403 (1979-05-18)
21	895	895.20	General	57 FR 58405 (1992-12-10)
21	895	895.101	Prosthetic hair fibers	48 FR 25136 (1983-06-03)
21	895	895.102	Powdered surgeon's glove	81 FR 91737 (2016-12-19)
21	895	895.103	Powdered patient examination glove	81 FR 91737 (2016-12-19)
21	895	895.104	Absorbable powder for lubricating a surgeon's glove	81 FR 91737 (2016-12-19)
21	898	N/A	Performance standard for electrode lead wires and patient cables	
21	898	898.11	Applicability	62 FR 25497 (1997-05-09)
21	898	898.12	Performance standard	62 FR 25497 (1997-05-09)
21	898	898.13	Compliance dates	62 FR 25497 (1997-05-09)
21	898	898.14	Exemptions and variances	62 FR 25497 (1997-05-09)
21	1100	N/A	Tobacco products subject to FDA authority	
21	1100	1100.1	Scope	88 FR 16552 (2023-03-20)
21	1100	1100.2	Requirements	88 FR 16552 (2023-03-20)
21	1100	1100.3	Definitions	88 FR 16552 (2023-03-20)
21	1100	1100.5	Exclusion from tobacco regulation	83 FR 11639 (2018-03-16)
21	1140	N/A	Cigarettes, smokeless tobacco, and other tobacco products	
21	1140	1140.1	Scope	81 FR 29102 (2016-05-10)

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C.F.R. Title	C.F.R. Part	C.F.R. Section	Section Title	Last Amended (__ FR ___ (YYYY-MM-DD)*
21	1140	1140.2	Purpose	81 FR 29102 (2016-05-10)
21	1140	1140.10	General responsibilities of manufacturers, distributors, and retailors	81 FR 29102 (2016-05-10)
21	1140	1140.16	Conditions of manufacture, sale, and distribution	75 FR 13230 (2010-03-19)
21	1140	1140.30	Scope of permissible forms of labeling and advertising	83 FR 13183 (2018-03-28)
21	1140	1140.32	Format and content requirements for labeling and advertising	75 FR 13230 (2010-03-19)
21	1270	N/A	Human tissue intended for transplantation	
21	1270	1270.1	Scope	*Revoked by* 87 FR 2045 (2022-01-13)
21	1270	1270.3	Definitions	*Revoked by* 87 FR 2045 (2022-01-13)
21	1271	N/A	Human cells, tissues, and cellular and tissue-based products	
21	1271	1271.1	What are the purpose and scope of this part?	81 FR 60212 (2016-08-31)
21	1271	1271.3	How does FDA define important terms in this part?	81 FR 60212 (2016-08-31)
21	1271	1271.10	Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?	69 FR 68680 (2004-11-24)
21	1271	1271.15	Are there any exceptions from the requirements of this part?	66 FR 5466 (2001-01-19)
21	1271	1271.20	If my HCT/P's do not meet the criteria in §1271.10, and I do not qualify for any of the exceptions in §1271.15, what regulations apply?	81 FR 60212 (2016-08-31)
21	1271	1271.45	What requirements does this subpart contain?	69 FR 68680 (2004-11-24)
21	1271	1271.145	Prevention of the introduction, transmission, or spread of communicable diseases	69 FR 68680 (2004-11-24)
21	1271	1271.155	Exemptions and alternatives	69 FR 68680 (2004-11-24)

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Federal Food, Drug, and Cosmetic Act

21 U.S.C. §§ 301 et seq.

CHAPTER I—SHORT TITLE (§ 1)

FFDCA § 1. Definitions [21 U.S.C. § 301]

This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

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CHAPTER II—DEFINITIONS (§ 201)

FFDCA § 201. Definitions [21 U.S.C. § 321]

For the purposes of this Act—

(a)

(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means

(1) commerce between any State or Territory and any place outside thereof, and

(2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means

(1) articles used for food or drink for man or other animals,

(2) chewing gum, and

(3) articles used for components of any such article.

(g)

(1) The term "drug" means

(A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement.

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(2) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor.

(h)

(1) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

(2) The term "counterfeit device" means a device which, or the container, packaging, or labeling of which, without authorization, bears a trademark, trade name, or other identifying mark or imprint, or any likeness thereof, or is manufactured using a design, of a device manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such device and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other device manufacturer, processor, packer, or distributor.

(i) The term "cosmetic" means

(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and

(2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any

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there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter

(1) upon any article or any of its containers or wrappers, or

(2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to June 25, 1938, it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q)

(1)

(A) Except as provided in clause (B), the term "pesticide chemical" means any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136 et seq.], including all active and inert ingredients of such pesticide. Notwithstanding any other provision of law, the term "pesticide" within such meaning includes ethylene oxide and propylene oxide when such substances are applied on food.

(B) In the case of the use, with respect to food, of a substance described in clause (A) to prevent, destroy, repel, or mitigate microorganisms (including bacteria, viruses, fungi, protozoa, algae, and slime), the following applies for purposes of clause (A):

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(i) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is applied for such use on food, or the substance is included for such use in water that comes into contact with the food, in the preparing, packing, or holding of the food for commercial purposes. The substance is not excluded under this subclause from such definition if the substance is ethylene oxide or propylene oxide, and is applied for such use on food. The substance is not so excluded if the substance is applied for such use on a raw agricultural commodity, or the substance is included for such use in water that comes into contact with the commodity, as follows:

(I) The substance is applied in the field.

(II) The substance is applied at a treatment facility where raw agricultural commodities are the only food treated, and the treatment is in a manner that does not change the status of the food as a raw agricultural commodity (including treatment through washing, waxing, fumigating, and packing such commodities in such manner).

(III) The substance is applied during the transportation of such commodity between the field and such a treatment facility.

(ii) The definition in such clause for the term "pesticide chemical" does not include the substance if the substance is a food contact substance as defined in section 409(h)(6), and any of the following circumstances exist: The substance is included for such use in an object that has a food contact surface but is not intended to have an ongoing effect on any portion of the object; the substance is included for such use in an object that has a food contact surface and is intended to have an ongoing effect on a portion of the object but not on the food contact surface; or the substance is included for such use in or is applied for such use on food packaging (without regard to whether the substance is intended to have an ongoing effect on any portion of the packaging). The food contact substance is not excluded under this subclause from such definition if any of the following circumstances exist: The substance is applied for such use on a semipermanent or permanent food contact surface (other than being applied on food packaging); or the substance is included for such use in an object that has a semipermanent or permanent food contact surface (other than being included in food packaging) and the substance is intended to have an ongoing effect on the food contact surface.

With respect to the definition of the term "pesticide" that is applicable to the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. § 136 et seq.], this clause does not exclude any substance from such definition.

(2) The term "pesticide chemical residue" means a residue in or on raw agricultural commodity or processed food of—

(A) a pesticide chemical; or

(B) any other added substance that is present on or in the commodity or food primarily as a result of the metabolism or other degradation of a pesticide chemical.

(3) Notwithstanding subparagraphs (1) and (2), the Administrator may by regulation except a substance from the definition of "pesticide chemical" or "pesticide chemical residue" if—

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(A) its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food; and

(B) the Administrator, after consultation with the Secretary, determines that the substance more appropriately should be regulated under one or more provisions of this Act other than sections 402(a)(2)(B) and 408.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or

(2) a pesticide chemical; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1958, pursuant to this Act, the Poultry Products Inspection Act [21 U.S.C. § 451 et seq.] or the Meat Inspection Act of March 4, 1907, as amended and extended [21 U.S.C. § 601 et seq.];

(5) a new animal drug; or

(6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.

(t)

(1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.

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(u) The term "safe" as used in paragraph (s) of this section and in sections 409, 512, 571, and 721, has reference to the health of man or animal.

(v) The term "new animal drug" means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,—

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a "new animal drug" if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

(w) The term "animal feed", as used in paragraph ([v]), in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal.

(x) The term "informal hearing" means a hearing which is not subject to section 554, 556, or 557 of Title 5 of the United States Code and which provides for the following:

(1) The presiding officer in the hearing shall be designated by the Secretary from officers and employees of the Department who have not participated in any action of the Secretary which is the subject of the hearing and who are not directly responsible to an officer or employee of the Department who has participated in any such action.

(2) Each party to the hearing shall have the right at all times to be advised and accompanied by an attorney.

(3) Before the hearing, each party to the hearing shall be given reasonable notice of the matters to be considered at the hearing, including a comprehensive statement of the basis for the action taken or proposed by the Secretary which is the subject of the hearing and a general summary of the information which will be presented by the Secretary at the hearing in support of such action.

(4) At the hearing the parties to the hearing shall have the right to hear a full and complete statement of the action of the Secretary which is the subject of the hearing together with the information and reasons supporting such action, to conduct reasonable questioning, and to present any oral or written information relevant to such action.

(5) The presiding officer in such hearing shall prepare a written report of the hearing to which shall be attached all written material presented at the hearing. The participants in the hearing shall be

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given the opportunity to review and correct or supplement the presiding officer's report of the hearing.

(6) The Secretary may require the hearing to be transcribed. A party to the hearing shall have the right to have the hearing transcribed at his expense. Any transcription of a hearing shall be included in the presiding officer's report of the hearing.

(y) The term "saccharin" includes calcium saccharin, sodium saccharin, and ammonium saccharin.

(z) The term "infant formula" means a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk.

(aa) The term "abbreviated drug application" means an application submitted under section 505(j) for the approval of a drug that relies on the approved application of another drug with the same active ingredient to establish safety and efficacy, and—

(1) in the case of section 306, includes a supplement to such an application for a different or additional use of the drug but does not include a supplement to such an application for other than a different or additional use of the drug, and

(2) in the case of sections 307 and 308, includes any supplement to such an application.

(bb) The term "knowingly" or "knew" means that a person, with respect to information—

(1) has actual knowledge of the information, or

(2) acts in deliberate ignorance or reckless disregard of the truth or falsity of the information.

(cc) For purposes of section 306, the term "high managerial agent"—

(1) means—

(A) an officer or director of a corporation or an association,

(B) a partner of a partnership, or

(C) any employee or other agent of a corporation, association, or partnership,

having duties such that the conduct of such officer, director, partner, employee, or agent may fairly be assumed to represent the policy of the corporation, association, or partnership, and

(2) includes persons having management responsibility for—

(A) submissions to the Food and Drug Administration regarding the development or approval of any drug product,

(B) production, quality assurance, or quality control of any drug product, or

(C) research and development of any drug product.

(dd) For purposes of sections 306 and 307, the term "drug product" means a drug subject to regulation under section 505, 512, or 802 of this Act or under section 351 of the Public Health Service Act.

(ee) The term "Commissioner" means the Commissioner of Food and Drugs.

(ff) The term "dietary supplement"—

(1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

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(A) a vitamin;

(B) a mineral;

(C) an herb or other botanical;

(D) an amino acid;

(E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or

(F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E);

(2) means a product that—

(A)

(i) is intended for ingestion in a form described in section 411(c)(1)(B)(i); or

(ii) complies with section 411(c)(1)(B)(ii);

(B) is not represented for use as a conventional food or as a sole item of a meal or the diet; and

(C) is labeled as a dietary supplement; and

(3) does—

(A) include an article that is approved as a new drug under section 505 or licensed as a biologic under section 351 of the Public Health Services Act and was, prior to such approval, certification, or license, marketed as a dietary supplement or as a food unless the Secretary has issued a regulation, after notice and comment, finding that the article, when used as or in a dietary supplement under the conditions of use and dosages set forth in the labeling for such dietary supplement, is unlawful under section 402(f); and

(B) not include—

(i) an article that is approved as a new drug under section 505, certified as an antibiotic under section 507,* or licensed as a biologic under section 351 of the Public Health Services Act, or

(ii) an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public,

which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act.

Except for purposes of sections 201(g) and section 417, a dietary supplement shall be deemed to be a food within the meaning of this Act.

(gg) The term "processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, or milling.

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* So in law. Section 507 was repealed by Pub. L. 105-115, § 125(b)(1), Nov 21, 1997, 1111 Stat 2325.

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(hh) The term "Administrator" means the Administrator of the United States Environmental Protection Agency.

(ii) The term "compounded positron emission tomography drug"—

(1) means a drug that—

(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.

(jj) The term "antibiotic drug" means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.

(kk) The term "priority supplement" means a drug application referred to in section 101(4) of the Food and Drug Administration Modernization Act of 1997 (111 Stat. 2298).

(ll)

(1) The term "single-use device" means a device that is intended for one use, or on a single patient during a single procedure.

(2)

(A) The term "reprocessed", with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.

(B) A single-use device that meets the definition under clause (A) shall be considered a reprocessed device without regard to any description of the device used by the manufacturer of the device or other persons, including a description that uses the term "recycled" rather than the term "reprocessed".

(3) The term "original device" means a new, unused single-use device.

(mm)

(1) The term "critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact normally sterile tissue or body spaces during use.

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(2) The term "semi-critical reprocessed single-use device" means a reprocessed single-use device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.

(nn) The term "major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

(oo) The term "minor species" means animals other than humans that are not major species.

(pp) The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.

(qq) The term "major food allergen" means any of the following:

(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).

(rr)

(1) The term "tobacco product" means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product).

(2) The term "tobacco product" does not mean an article that is a drug under subsection (g)(1), a device under subsection (h), or a combination product described in section 503(g).

(3) The products described in paragraph (2) shall be subject to Chapter V of this Act.

(4) A tobacco product shall not be marketed in combination with any other article or product regulated under this Act (including a drug, biologic, food, cosmetic, medical device, or a dietary supplement).

(5) The term "tobacco product" does not mean an article that is a food under paragraph (f), if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

(ss) The term "critical food" means a food that is—

(1) an infant formula; or

(2) a medical food, as defined in section 5(b)(3) of the Orphan Drug Act..

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CHAPTER III—PROHIBITED ACTS AND PENALTIES (§§ 301-311)

FFDCA § 301. Prohibited acts [21 U.S.C. § 331]

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, 564 or 607.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 605, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 416, 417, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 605, 611, 760, 761, 909, or 920 or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

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(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) [Repealed]

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).

(q)

(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

(C) to comply with a requirement under section 522 or 913.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(3) The failure to comply with any requirement under section 524B(b)(2) (relating to ensuring device cybersecurity)

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(r) The movement of a device, drug, or tobacco product in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device, drug, or tobacco product as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), the distribution of drugs in violation of section 503(e), failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable, or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

. . . .

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

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(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food or a drug by, with the assistance of, or at the direction of, a person debarred from such activity under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to comply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 416.

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 604, 760, or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761 or required under section 605(a)) submitted to the Secretary.

(jj)

(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 503B.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

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(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h); or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 512.

(mm) The failure to submit a report or provide a notification required under section 417(d).

(nn) The falsification of a report or notification required under section 417(d).

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

(qq)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that

(1) the product is approved by the Food and Drug Administration;

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(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration; including any such statement or representation rendering the product misbranded under section 903.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.

(vv) The failure to comply with the requirements under section 419.

(ww) The failure to comply with section 420.

(xx) The refusal or failure to follow an order under section 423.

(yy) The knowing and willful failure to comply with the notification requirement under section 417(h).

(zz) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.

(aaa) The failure to register in accordance with section 801(s).

(bbb) The failure to notify the Secretary in violation of section 568.

(ccc)

(1) The resale of a compounded drug that is labeled ''not for resale'' in accordance with section 503B.

(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.

(ddd)

(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term ''plastic microbead'' means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term ''rinse-off cosmetic'' includes toothpaste.

(eee) The failure to comply with any order issued under section 569D.

(fff)

(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

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(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing upon any device or container, packaging, or labeling thereof so as to render such device a counterfeit device.

(3) The doing of any act which causes a device to be a counterfeit device, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit device.

(ggg) The failure of a sponsor of a product approved under accelerated approval pursuant to section 506(c)—

(1) to conduct with due diligence any postapproval study required under section 506(c) with respect to such product; or

(2) to submit timely reports with respect to such product in accordance with section 506B(a)(2).

(hhh) The failure to register or submit listing information in accordance with section 607.

(iii) The refusal or failure to follow an order under section 611.

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FFDCA § 302. Injunction proceedings [21 U.S.C. § 332]

(a) Jurisdiction of courts

The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown to restrain violations of section 301, except paragraphs (h), (i), and (j).

(b) Violation of injunction

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury.

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FFDCA § 303. Penalties [21 U.S.C. § 333]

(a) Violation of section 301; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) . . . , if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

. . . .

(c) Exceptions in certain cases of good faith, etc.

No person shall be subject to the penalties of subsection (a)(1) of this section,

(1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or

(2) for having violated section 301(a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this chapter designating this chapter or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce . . . .

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FFDCA § 304. Seizure [21 U.S.C. § 334]

(a) Grounds and jurisdiction

(1) Any article of food, drug, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, or which may not, under the provisions of section 301(ll), 404, or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which the article is found. . . .

(2) The following shall be liable to be proceeded against at any time on libel of information and condemned in any district court of the United States or United States court of a Territory within the jurisdiction of which they are found:

(A) Any drug that is a counterfeit drug,

(B) Any container of a counterfeit drug,

(C) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit drug or drugs,

(D) Any adulterated or misbranded device,

(E) Any adulterated or misbranded tobacco product,

(F) Any device that is a counterfeit device,

(G) Any container, packaging, or labeling of a counterfeit device, and

(H) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit device or devices.

. . . .

(b) Procedure; multiplicity of pending proceedings

The article, equipment, or other thing proceeded against shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in

(1) any district selected by the claimant where one of such proceedings is pending; or

(2) a district agreed upon by stipulation between the parties.

. . . .

(c) Availability of samples of seized goods prior to trial

The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized and

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a true copy of the analysis, if any, on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

(d) Disposition of goods after decree of condemnation; claims for remission or mitigation of forfeitures

(1) Any food, drug, device, tobacco product, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold. After entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this chapter, under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. If the article was imported into the United States and the person seeking its release establishes

(A) that the adulteration, misbranding, or violation did not occur after the article was imported, and

(B) that he had no cause for believing that it was adulterated, misbranded, or in violation before it was released from customs custody,

the court may permit the article to be delivered to the owner for exportation in lieu of destruction upon a showing by the owner that all of the conditions of section 801(e) can and will be met. . . .

(g) Administrative restraint; detention orders

(1) If during an inspection conducted under section 704 of a facility or a vehicle, a device, drug, or tobacco product which the officer or employee making the inspection has reason to believe is adulterated or misbranded is found in such facility or vehicle, such officer or employee may order the device, drug, or tobacco product detained (in accordance with regulations prescribed by the Secretary) for a reasonable period which may not exceed twenty days unless the Secretary determines that a period of detention greater than twenty days is required to institute an action under subsection (a) or section 302, in which case he may authorize a detention period of not to exceed thirty days. Regulations of the Secretary prescribed under this paragraph shall require that before a device, drug, or tobacco product may be ordered detained under this paragraph the Secretary or an officer or employee designated by the Secretary approve such order. A detention order under this paragraph may require the labeling or marking of a device, drug, or tobacco product during the period of its detention for the purpose of identifying the device, drug, or tobacco product as detained. Any person who would be entitled to claim a device, drug, or tobacco product if it were seized under subsection (a) may appeal to the Secretary a detention of such device, drug, or tobacco product under this paragraph. Within five days of the date an appeal of a detention is filed with the Secretary, the Secretary shall after affording opportunity for an informal hearing by order confirm the detention or revoke it.

. . . .

(h) Administrative detention of foods

(1) Detention authority

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(A) In general

An officer or qualified employee of the Food and Drug Administration may order the detention, in accordance with this subsection, of any article of food that is found during an inspection, examination, or investigation under this chapter conducted by such officer or qualified employee, if the officer or qualified employee has reason to believe that such article is adulterated or misbranded.

. . . .

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FFDCA § 305. Hearing before report of criminal violation [21 U.S.C. § 335]

Before any violation of this chapter is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

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FFDCA § 306. Debarment, temporary denial of approval, and suspension [21 U.S.C. § 335A]

(a) Mandatory debarment; certain drug applications

(1) Corporations, partnerships, and associations

If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any abbreviated drug application, the Secretary shall debar such person from submitting, or assisting in the submission of, any such application.

(2) Individuals

If the Secretary finds that an individual has been convicted of a felony under Federal law for conduct—

(A) relating to the development or approval, including the process for development or approval, of any drug product, or

(B) otherwise relating to the regulation of any drug product under this Act,

the Secretary shall debar such individual from providing services in any capacity to a person that has an approved or pending drug product application.

. . . .

(c) Debarment period and considerations

(1) Effect of debarment

The Secretary—

(A) shall not accept or review (other than in connection with an audit under this section) any abbreviated drug application submitted by or with the assistance of a person debarred under subsection (a)(1) or (b)(2)(A) during the period such person is debarred,

(B) shall, during the period of a debarment under subsection (a)(2) or (b)(2)(B), debar an individual from providing services in any capacity to a person that has an approved or pending drug product application and shall not accept or review (other than in connection with an audit under this section) an abbreviated drug application from such individual, and

(C) shall, if the Secretary makes the finding described in paragraph (6) or (7) of section 307(a), assess a civil penalty in accordance with section 307.

. . . .

(e) Publication and list of debarred persons

The Secretary shall publish in the Federal Register the name of any person debarred under subsection (a) or (b), the effective date of the debarment, and the period of the debarment. The Secretary shall also maintain and make available to the public a list, updated no less often than quarterly, of such persons, of the effective dates and minimum periods of such debarments, and of the termination of debarments.

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FFDCA § 307. Civil penalties [21 U.S.C. § 335b]

(a) In general

Any person that the Secretary finds—

(1) knowingly made or caused to be made, to any officer, employee, or agent of the Department of Health and Human Services, a false statement or misrepresentation of a material fact in connection with an abbreviated drug application,

(2) bribed or attempted to bribe or paid or attempted to pay an illegal gratuity to any officer, employee, or agent of the Department of Health and Human Services in connection with an abbreviated drug application,

(3) destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document or other material evidence which was the property of or in the possession of the Department of Health and Human Services for the purpose of interfering with that Department's discharge of its responsibilities in connection with an abbreviated drug application,

(4) knowingly failed to disclose, to an officer or employee of the Department of Health and Human Services, a material fact which such person had an obligation to disclose relating to any drug subject to an abbreviated drug application,

(5) knowingly obstructed an investigation of the Department of Health and Human Services into any drug subject to an abbreviated drug application,

(6) is a person that has an approved or pending drug product application and has knowingly—

(A) employed or retained as a consultant or contractor, or

(B) otherwise used in any capacity the services of,

a person who was debarred under section 306, or

(7) is an individual debarred under section 306 and, during the period of debarment, provided services in any capacity to a person that had an approved or pending drug product application,

shall be liable to the United States for a civil penalty for each such violation in an amount not to exceed $250,000 in the case of an individual and $1,000,000 in the case of any other person.

. . . .

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FFDCA § 309. Report of minor violations [21 U.S.C. § 336]

Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

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FFDCA § 311. Extraterritorial jurisdiction [21 U.S.C. § 337a]

There is extraterritorial jurisdiction over any violation of this chapter relating to any article regulated under this chapter if such article was intended for import into the United States or if any act in furtherance of the violation was committed in the United States.

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CHAPTER IV—FOOD (§§ 401-424)

FFDCA § 401. Definitions and standards for food [21 U.S.C. § 341]

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

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FFDCA § 402. Adulterated Food [21 U.S.C. § 342]

A food shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health;

(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 406; or

(B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 408(a); or

(C) if it is or if it bears or contains

(i) any food additive that is unsafe within the meaning of section 409; or

(ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512; or

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

(b) Absence, substitution, or addition of constituents

(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

(2) if any substance has been substituted wholly or in part therefore; or

(3) if damage or inferiority has been concealed in any manner; or

(4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) Color additives

If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a).

(d) Confectionery containing alcohol or nonnutritive substance

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If it is confectionery, and —

(1) has partially or completely imbedded therein any nonnutritive object, except that this subparagraph shall not apply in the case of any nonnutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health;

(2) bears or contains any alcohol other than alcohol not in excess of one-half of 1 per centum by volume derived solely from the use of flavoring extracts, except that this clause shall not apply to confectionery which is introduced of delivered for introduction into, or received or held for sale in, interstate commerce if the sale of such confectionery is permitted under the laws of the State in which such confectionery is intended to be offered for sale; or

(3) bears or contains any nonnutritive substance, except that this subparagraph shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Act, except that the Secretary may, for the purpose of avoiding or resolving uncertainty as to the application of this subparagraph, issue regulations allowing of prohibiting the use of particular nonnutritive substance.

(e) Oleomargarine containing filthy, putrid, etc., matter

If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

(f) Dietary supplement or ingredient: safety

(1) If it is a dietary supplement or contains a dietary ingredient that —

(A) presents a significant or unreasonable risk of illness or injury under —

(i) conditions of use recommended or suggested in labeling, or

(ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use;

(B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

(C) the Secretary declares to pose an imminent hazard to public health or safety, except that the authority to make such declaration shall not be delegated and the Secretary shall promptly after such a declaration initiate a proceeding in accordance with sections 554 and 556 of title 5, United States Code, to affirm or withdraw the declaration; or

(D) is or contains a dietary ingredient that renders it adulterated under paragraph (a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.

In any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated. The court shall decide any issue under this paragraph on a de novo basis.

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(2) Before the Secretary may report to a United States attorney a violation of [sub]paragraph (1)(A) for a civil proceeding, the person against whom such proceeding would be initiated shall be given appropriate notice and the opportunity to present views, orally and in writing, at least 10 days before such notice, with regard to such proceeding.

(g) Dietary supplement: manufacturing practices

(1) If it is a dietary supplement and it has been prepared, packed, or help under conditions that do not meet current good manufacturing practice regulations, including regulations requiring, when necessary, expiration date labeling, issued by the Secretary under subparagraph (2).

(2) The Secretary may by regulation prescribe good manufacturing practices for dietary supplements. Such regulations shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of current good manufacturing practice may be imposed unless such standard is included in a regulation promulgated after notice and opportunity for comment in accordance with chapter 5 of title 5, United States Code.

(h) Reoffer of food previously denied admission

If it is an article of food imported or offered for import into the United States and the article of food has previously been refused admission under section 801(a), unless the person reoffering the article affirmatively establishes, at the expense of the owner or consignee of the article, that the article complies with the applicable requirements of this Act, as determined by the Secretary.

(i) If it is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with regulations promulgated under section 416.

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FFDCA § 403. Misbranded Food [21 U.S.C. § 343]

A food shall be deemed to be misbranded—

(a) False or misleading label

If

(1) its labeling is false or misleading in any particular, or

(2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).

(b) Offer for sale under another name

If it is offered for sale under the name of another food.

(c) Imitation of another food

If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) Misleading container

If its container is so made, formed, or filled as to be misleading.

(e) Package form

If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count,

except that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

. . . .

(j) Representation for special dietary use

If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) Artificial flavoring, artificial coloring, or chemical preservatives

If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact, except that to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream. The provisions of this paragraph with respect to chemical

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preservatives shall not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the produce of the soil.

(l) Pesticide chemicals on raw agricultural commodities

If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the function of such chemical, except that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(m) Color additives

If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721.

. . . .

(q) Nutrition information

(1) Except as provided in subparagraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)

(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat, in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this Act before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

. . . .

(r) Nutrition levels and health-related claims

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(1) Except as provided in clauses (A) through (C) of subparagraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of the food unless the claim is made in accordance with subparagraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label of labeling of the food to a disease of a health-related condition unless the claim is made in accordance with subparagraph (3) or (5)(D).

A statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph and a claim subject to clause (A) is not subject to clause (B).

(2)

(A) Except as provided in subparagraphs (4)(A)(ii) and (4)(A)(iii) and clauses (A) through (C) of subparagraph (5), a claim described in subparagraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food.

. . . .

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See nutrition information for ____ content." The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in tis clause, the Secretary shall take into account the significance of the food in the total daily diet.

. . . .

(3)

(A) Except as provided in subparagraph (5), a claim described in subparagraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under clause (B), and

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(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by subparagraph (2)(B).

(B)

(i) The Secretary shall promulgate regulations authorizing claims of the type described in subparagraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in subclause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by paragraph (q)(1) or (q)(2) and a disease of health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in subclause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in subclause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of the total daily diet.

. . . .

(5)

(A) This paragraph does not apply to infant formulas subject to section 412(h) and medical foods as defined in section 5(b) of the Orphan Drug Act.

(B) Subclauses (iii) through (v) of subparagraph (2)(A) and subparagraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A subparagraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 401 shall not be subject to subparagraph (2)(A)(i) or (2)(B).

(D) A subparagraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to subparagraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(6) For purposes of paragraph (r)(1)(B), a statement for a dietary supplement may be made if—

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure of function in humans, characterizes the documented mechanism

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by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient.

(B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and

(C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

A statement under this subparagraph may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. If the manufacturer of a dietary supplement proposes to make a statement described in the first sentence of this subparagraph in the labeling of the dietary supplement, the manufacturer shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement with such statement that such a statement is being made.

. . . .

(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

(i) enable consumers to develop and maintain healthy dietary practices;

(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.

(s) Dietary Supplements

If—

(1) it is a dietary supplement; and

(2)

(A) the label or labeling of the supplement fails to list—

(i) the name of each ingredient of the supplement that is described in section 201(ff); and

(ii)

(I) the quantity of such ingredient; or

(II) with respect to a proprietary blend of such ingredients, the total quantity of all ingredients in the blend;

(B) the label or labeling of the dietary supplement fails to identify the product by using the term "dietary supplement", which term may be modified with the name of such an ingredient;

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(C) the supplement contains an ingredient described in section 201(ff)(1)(C), and the label or labeling of the supplement fails to identify any part of the plant from which the ingredient is derived;

(D) the supplement—

(i) is covered by the specifications of an official compendium;

(ii) is represented as conforming to the specifications of an official compendium; and

(iii) fails to so conform; or

(E) the supplement—

(i) is not covered by the specifications of an official compendium; and

(ii)

(I) fails to have the identity and strength that the supplement is represented to have; or

(II) fails to meet the quality (including tablet or capsule disintegration), purity, or compositional specifications, based on validated assay or other appropriate methods, that the supplement is represented to meet.

A dietary supplement shall not be deemed misbranded solely because its label or labeling contains directions or conditions of use or warnings.

. . . .

(v) Failure to label; health threat

If—

(1) it fails to bear a label required by the Secretary under section 801(n)(1) (relating to food refused admission into the United States);

(2) the Secretary finds that the food presents a threat of serious adverse health consequences or death to humans or animals; and

(3) upon or after notifying the owner of consignee involved that the label is required under section 801, the Secretary informs the owner or consignee that the food presents such a threat.

(w) Major food allergen labeling requirements

(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

(A) the word "Contains", followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

(B) the common or usual name of the major food allergen in the list of ingredients required under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived . . . .

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FFDCA § 403B. Dietary supplement labeling exemptions [21 U.S.C. § 343-2]

(a) In general

A publication, including an article, a chapter in a book, or an official abstract of a peer-reviewed scientific publication that appears in an article and was prepared by the author or the editors of the publication, which is reprinted in its entirety, shall not be defined as labeling when used in connection with the sale of a dietary supplement to consumers when it—

(1) is not false or misleading;

(2) does not promote a particular manufacturer or brand of a dietary supplement;

(3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement;

(4) if displayed in an establishment, is physically separate from the dietary supplements; and

(5) does not have appended to it any information by sticker or any other method.

(b) Application

Subsection (a) shall not apply to or restrict a retailer or wholesaler of dietary supplements in any way whatsoever in the sale of books or other publications as a part of the business of such retailer or wholesaler.

(c) Burden of proof

In any proceeding brought under subsection (a), the burden of proof shall be on the United States to establish that an article or other such matter is false or misleading.

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FFDCA § 404. Emergency permit control [21 U.S.C. § 344]

(a) Conditions on manufacturing, processing, etc., as health measure

Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

(b) Violation of permit; suspension and reinstatement

The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

(c) Inspection of permit-holding establishments

Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

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FFDCA § 406. Tolerances for poisonous or deleterious substances in food; regulations [21 U.S.C. § 346]

Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

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FFDCA § 408. Tolerances and exemptions for pesticide chemical residues [21 U.S.C. § 346a]

(a) Requirement for tolerance or exemption

(1) General rule

Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 402(a)(2)(B) unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modification, shall mean a raw agricultural commodity or processed food.

. . . .

(4) Effect of tolerance or exemption

While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 402(a)(1).

. . . .

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FFDCA § 409. Food additives [21 U.S.C. § 348]

(a) Unsafe food additives; exception for conformity with exemption or regulation

A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (j) of this section;

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

(B) a notification submitted under subsection (h) that is effective.

While such a regulation relating to a food additive, or such a notification under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).

(b) Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation

(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

. . . .

(c) Approval or denial of petition; time for issuance of order; evaluation of data; factors

(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

. . . .

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

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(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds

(i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and

(ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

. . . .

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

(d) Regulation issued on Secretary's initiative

The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

. . . .

(h) Notification relating to food contact substance

(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

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. . . .

(2)

(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

. . . .

(6) In this section, the term "food contact substance" means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.

. . . .

(j) Exemptions for investigational use

Without regard to subsections (b) to (i), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

(k) Food additives intended for use in animal food

(1) In taking action on a petition under subsection (c) for, or for recognition of, a food additive intended for use in animal food, the Secretary shall review reports of investigations conducted in foreign countries, provided by the petitioner.

. . . .

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FFDCA § 411. Vitamins and minerals [21 U.S.C. § 350]

(a) Authority and limitations of Secretary; applicability

(1) Except as provided in paragraph (2)—

(A) the Secretary may not establish, under section 201(n), 401, or 403, maximum limits on the potency of any synthetic or natural vitamin or mineral within a food to which this section applies;

(B) the Secretary may not classify any natural or synthetic vitamin or mineral (or combination thereof) as a drug solely because it exceeds the level of potency which the Secretary determines is nutritionally rational or useful;

(C) the Secretary may not limit, under section 201(n), 401, or 403, the combination or number of any synthetic or natural—

(i) vitamin,

(ii) mineral, or

(iii) other ingredient of food,

within a food to which this section applies.

(2) Paragraph (1) shall not apply in the case of a vitamin, mineral, other ingredient of food, or food, which is represented for use by individuals in the treatment or management of specific diseases or disorders, by children, or by pregnant or lactating women. For purposes of this []paragraph, the term "children" means individuals who are under the age of twelve years.

(b) Labeling and advertising requirements for foods

(1) A food to which this section applies shall not be deemed under section 403 to be misbranded solely because its label bears, in accordance with section 403(i)(2), all the ingredients in the food or its advertising contains references to ingredients in the food which are not vitamins or minerals.

(2) The labeling for any food to which this section applies may not list its ingredients which are not dietary supplement ingredients described in section 201(ff)

(i) except as a part of a list of all the ingredients of such food, and

(ii) unless such ingredients are listed in accordance with applicable regulations under section 403.

To the extent that compliance with clause (i) of this subparagraph is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(c) Definitions

(1) For purposes of this section, the term "food to which this section applies" means a food for humans which is a food for special dietary use—

(A) which is or contains any natural or synthetic vitamin or mineral, and

(B) which—

(i) is intended for ingestion in tablet, capsule, powder, softgel, gelcap, or liquid form, or

(ii) if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet.

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(2) For purposes of paragraph (1) (B) (i), a food shall be considered as intended for ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure.

(3) For purposes of paragraph (1) and of section 403(j) insofar as that section is applicable to food to which this section applies, the term "special dietary use" as applied to food used by man means a particular use for which a food purports or is represented to be used, including but not limited to the following:

(A) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium.

(B) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake.

(C) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

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FFDCA § 413. New dietary ingredients [21 U.S.C. § 350b]

(a) In general

A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:

(1) The dietary supplement contains only dietary ingredients which have been present in the food supply as an article used for food in a form in which the food has not been chemically altered.

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

The Secretary shall keep confidential any information provided under paragraph (2) for 90 days following its receipt. After the expiration of such 90 days, the Secretary shall place such information on public display, except matters in the information which are trade secrets or otherwise confidential, commercial information.

(b) Petition

Any person may file with the Secretary a petition proposing the issuance of an order prescribing the conditions under which a new dietary ingredient under its intended conditions of use will reasonably be expected to be safe. The Secretary shall make a decision on such petition within 180 days of the date the petition is filed with the Secretary. For purposes of chapter 7 of Title 5, the decision of the Secretary shall be considered final agency action.

. . . .

(d) "New dietary ingredient" defined

For purposes of this section, the term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.

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FFDCA § 415. Registration of food facilities [21 U.S.C. § 350d]

(a) Registration

(1) In general

The Secretary shall by regulation require that any facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States be registered with the Secretary. To be registered—

(A) for a domestic facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary; and

(B) for a foreign facility, the owner, operator, or agent in charge of the facility shall submit a registration to the Secretary and shall include with the registration the name of the United States agent for the facility.

(2) Registration

An entity (referred to in this section as the "registrant") shall submit a registration under paragraph (1) to the Secretary containing information necessary to notify the Secretary of the name and address of each facility at which, and all trade names under which, the registrant conducts business, the e-mail address for the contact person of the facility or, in the case of a foreign facility, the United States agent for the facility, and, when determined necessary by the Secretary through guidance, the general food category (as identified under section 170.3 of title 21, Code of Federal Regulations, or any other food categories as determined appropriate by the Secretary, including by guidance) of any food manufactured, processed, packed, or held at such facility. The registration shall contain an assurance that the Secretary will be permitted to inspect such facility at the times and in the manner permitted by this Act. . . .

(b) Suspension of registration

(1) In general

If the Secretary determines that food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death to humans or animals, the Secretary may by order suspend the registration of a facility—

(A) that created, caused, or was otherwise responsible for such reasonable probability; or

(B)

(i) that knew of, or had reason to know of, such reasonable probability; and

(ii) packed, received, or held such food.

. . . .

(c) Facility

For purposes of this section:

(1) The term "facility" includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such

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term does not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer; or fishing vessels (except such vessels engaged in processing as defined in section 123.3(k) of title 21, Code of Federal Regulations).

(2) The term "domestic facility" means a facility located in any of the States or Territories.

(3)

(A) The term "foreign facility" means a facility that manufacturers, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States.

(B) A food may not be considered to have undergone further processing or packaging for purposes of subparagraph (A) solely on the basis that labeling was added or that any similar activity of a de minimis nature was carried out with respect to the food.

(d) Rule of construction

Nothing in this section shall be construed to authorize the Secretary to require an application, review, or licensing process for a facility to be registered, except with respect to the reinstatement of a registration that is suspended under subsection (b).

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FFDCA § 418. Hazard analysis and risk-based preventative controls [21 U.S.C. § 350g]

(a) In general

The owner, operator, or agent in charge of a facility shall, in accordance with this section, evaluate the hazards that could affect food manufactured, processed, packed, or held by such facility, identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards and provide assurances that such food is not adulterated under section 402 or misbranded under section 403(w), monitor the performance of those controls, and maintain records of this monitoring as a matter of routine practice.

(b) Hazard analysis

The owner, operator, or agent in charge of a facility shall—

(1) identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including—

(A) biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives; and

(B) hazards that occur naturally, or may be unintentionally introduced; and

(2) identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and

(3) develop a written analysis of the hazards.

(c) Preventive controls

The owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances that—

(1) hazards identified in the hazard analysis conducted under subsection (b)(1) will be significantly minimized or prevented;

(2) any hazards identified in the hazard analysis conducted under subsection (b)(2) will be significantly minimized or prevented and addressed, consistent with section 420, as applicable; and

(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under section 402 or misbranded under section 403(w).

(d) Monitoring of effectiveness

The owner, operator, or agent in charge of a facility shall monitor the effectiveness of the preventive controls implemented under subsection (c) to provide assurances that the outcomes described in subsection (c) shall be achieved.

(e) Corrective actions

The owner, operator, or agent in charge of a facility shall establish procedures to ensure that, if the preventive controls implemented under subsection (c) are not properly implemented or are found to be ineffective—

(1) appropriate action is taken to reduce the likelihood of recurrence of the implementation failure;

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(2) all affected food is evaluated for safety; and

(3) all affected food is prevented from entering into commerce if the owner, operator or agent in charge of such facility cannot ensure that the affected food is not adulterated under section 402 or misbranded under section 403(w).

(f) Verification

The owner, operator, or agent in charge of a facility shall verify that—

(1) the preventive controls implemented under subsection (c) are adequate to control the hazards identified under subsection (b);

(2) the owner, operator, or agent is conducting monitoring in accordance with subsection (d);

(3) the owner, operator, or agent is making appropriate decisions about corrective actions taken under subsection (e);

(4) the preventive controls implemented under subsection (c) are effectively and significantly minimizing or preventing the occurrence of identified hazards, including through the use of environmental and product testing programs and other appropriate means; and

(5) there is documented, periodic reanalysis of the plan under subsection (i) to ensure that the plan is still relevant to the raw materials, conditions and processes in the facility, and new and emerging threats.

(g) Recordkeeping

The owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under subsection (c), instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under subsection (f)(4), instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.

(h) Written plan and documentation

The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.

(i) Requirement to reanalyze

The owner, operator, or agent in charge of a facility shall conduct a reanalysis under subsection (b) whenever a significant change is made in the activities conducted at a facility operated by such owner, operator, or agent if the change creates a reasonable potential for a new hazard or a significant increase in a previously identified hazard or not less frequently than once every 3 years, whichever is earlier. . . .

(j) Exemption for seafood, juice, and low-acid canned food facilities subject to HACCP

(1) In general

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This section shall not apply to a facility if the owner, operator, or agent in charge of such facility is required to comply with, and is in compliance with, 1 of the following standards and regulations with respect to such facility:

(A) The Seafood Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

(B) The Juice Hazard Analysis Critical Control Points Program of the Food and Drug Administration.

(C) The Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers standards of the Food and Drug Administration (or any successor standards).

. . . .

(k) Exception for activities of facilities subject to section 419

This section shall not apply to activities of a facility that are subject to section 419

. . . .

(m) Authority with respect to certain facilities

The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (other than fruits and vegetables) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.

(n) Regulations

(1) In general

Not later than 18 months after January 4, 2011, the Secretary shall promulgate regulations—

(A) to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under this section; and

(B) to define, for purposes of this section, the terms "small business" and "very small business", taking into consideration the study described in subsection (l)(5).

. . . .

(3) Content

The regulations promulgated under paragraph (1)(A) shall—

(A) provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm;

(B) comply with chapter 35 of Title 44 (commonly known as the "Paperwork Reduction Act"), with special attention to minimizing the burden (as defined in section 3502(2) of such title) on the facility, and collection of information (as defined in section 3502(3) of such title), associated with such regulations;

(C) acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods; and

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(D) not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventative controls, except in the case of negotiated enforcement resolutions that may require such a consultant or third party.

(4) Rule of construction

Nothing in this subsection shall be construed to provide the Secretary with the authority to prescribe specific technologies, practices, or critical controls for an individual facility.

. . . .

(o) Definitions

For purposes of this section:

(1) Critical control point

The term "critical control point" means a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

(2) Facility

The term "facility" means a domestic facility or a foreign facility that is required to register under section 415.

(3) Preventive controls

The term "preventive controls" means those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis conducted under subsection (b) and that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis. Those procedures, practices, and processes may include the following:

(A) Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.

(B) Supervisor, manager, and employee hygiene training.

(C) An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.

(D) A food allergen control program.

(E) A recall plan.

(F) Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations).

(G) Supplier verification activities that relate to the safety of food.

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CHAPTER V—DRUGS AND DEVICES (§§ 501-573)

PART A – DRUGS AND DEVICES (§§ 501-524)

FFDCA § 501. Adulterated drugs and devices [21 U.S.C. § 351]

A drug or device shall be deemed to be adulterated—

(a) Poisonous, insanitary, etc., ingredients; adequate controls in manufacture

(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or

(2)

(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or

(C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or

(3) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(4) if

(A) it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a), or

(B) it is a color additive the intended use of which in or on drugs or devices is for purposes of coloring only and is unsafe within the meaning of section 721(a); or

(5) if it is a new animal drug which is unsafe within the meaning of section 512; or

(6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.

(b) Strength, quality, or purity differing from official compendium

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If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. . . .. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. . . .

(c) Misrepresentation of strength, etc., where drug is unrecognized in compendium

If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) Mixture with or substitution of another substance

If it is a drug and any substance has been

(1) mixed or packed therewith so as to reduce its quality or strength or

(2) substituted wholly or in part therefor.

. . . .

(f) Certain class III devices

(1) If it is a class III device—

(A)

(i) which is required by an order issued under subsection (b) of section 515 to have an approval under such section of an application for premarket approval and which is not exempt from section 515 under section 520(g), and

(ii)

(I) for which an application for premarket approval or a notice of completion of a product development protocol was not filed with the Secretary within the ninety-day period beginning on the date of the issuance of such order, or

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B)

(i) which was classified under section 513(f) into class III, which under section 515(a) is required to have in effect an approved application for premarket approval, and which is not exempt from section 515 under section 520(g), and

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 520(l) into class III, which under such section is required to have in effect an approved application under section 515, and which has an application which has been suspended or is otherwise not in effect.

(g) Banned devices

If it is a banned device.

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(h) Manufacture, packing, storage, or installation of device not in conformity with applicable requirements or conditions

If it is a device and the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) or an applicable condition prescribed by an order under section 520(f)(2).

(i) Failure to comply with requirements under which device was exempted for investigational use

If it is a device for which an exemption has been granted under section 520(g) for investigational use and the person who was granted such exemption or any investigator who uses such device under such exemption fails to comply with a requirement prescribed by or under such section.

(j) Delayed, denied, or limited inspection; refusal to permit entry or inspection

If it is a drug or device and it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.

For purposes of paragraph (a)(2)(B), the term "current good manufacturing practice" includes the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products.

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FFDCA § 502. Misbranded drugs and devices [21 U.S.C. § 352]

A drug or device shall be deemed to be misbranded—

(a) False or misleading label

(1) If its labeling is false or misleading in any particular. . . .

(b) Package form; contents of label

If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

. . . .

(e) Designation of drugs or devices by established names

(1)

(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the

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Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(2) If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name (as defined in subparagraph (4)) prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such device, except that to the extent compliance with the requirements of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(3) As used in subparagraph (1), the term "established name", with respect to a drug or ingredient thereof, means

(A) the applicable official name designated pursuant to section 508, or

(B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or

(C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient . . . .

(4) As used in subparagraph (2), the term "established name" with respect to a device means

(A) the applicable official name of the device designated pursuant to section 508,

(B) if there is no such name and such device is an article recognized in an official compendium, then the official title thereof in such compendium, or

(C) if neither clause (A) nor clause (B) of this subparagraph applies, then any common or usual name of such device.

(f) Directions for use and warnings on label

Unless its labeling bears

(1) adequate directions for use; and

(2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

. . . .

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(g) Representations as recognized drug; packing and labeling; inconsistent requirements for designation of drug

If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein. The method of packing may be modified with the consent of the Secretary. . . .

(h) Deteriorative drugs; packing and labeling

If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i) Drug; misleading container; imitation; offer for sale under another name

(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or

(2) if it is an imitation of another drug; or

(3) if it is offered for sale under the name of another drug.

(j) Health-endangering when used as prescribed

If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

. . . .

(m) Color additives; packing and labeling

If it is a color additive the intended use of which is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 721.

(n) Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; false advertising; labeling; construction of the Convention on Psychotropic Substances

In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of

(1) the established name as defined in paragraph (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof,

(2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under paragraph (e), and

(3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in

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accordance with section 701(a), and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text:

> "You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.",

except that

> (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and
>
> (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52-57).

This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m). . . .

In the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a clear, conspicuous, and neutral manner.

(o) Drugs or devices from nonregistered establishments

If it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510, if it is a drug and was imported or offered for import by a commercial importer of drugs not duly registered under section 801(s), if it was not included in a list required by section 510(j), if a notice or other information respecting it was not provided as required by such section or section 510(k), or if it does not bear such symbols from the uniform system for identification of devices prescribed under section 510(e) as the Secretary by regulation requires.

(p) Packaging or labeling of drugs in violation of regulations

If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

(q) Restricted devices using false or misleading advertising or used in violation of regulations

In the case of any restricted device distributed or offered for sale in any State, if

> (1) its advertising is false or misleading in any particular, or
>
> (2) it is sold, distributed, or used in violation of regulations prescribed under section 520(e).

(r) Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter

In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that device

> (1) a true statement of the device's established name as defined in subsection (e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, and

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(2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

Except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement and no advertisement of a restricted device, published after the effective date of this paragraph shall, with respect to the matters specified in this paragraph or covered by regulations issued hereunder, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52-55). This paragraph shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m).

. . . .

(w) New animal drugs

If it is a new animal drug—

(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A);

(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or 572(h), or that has not been indexed under section 572 and its label bears the statement set forth in section 572(h); or

(3) for which an application has been approved under section 512 and the labeling of such drug does not include the application number in the format: "Approved by FDA under (A)NADA # xxx-xxx", except that this subparagraph shall not apply to representative labeling required under section 514.1(b)(3)(v)(b) of title 21, Code of Federal Regulations (or any successor regulation) for animal feed bearing or containing a new animal drug.

. . . .

(ee) Nonprescription drug subject to regulation

If it is a nonprescription drug that is subject to section 505G, is not the subject of an application approved under section 505, and does not comply with the requirements under section 505G.

(ff) Drugs manufactured, prepared, propagated, compounded, or processed in facilities for which fees have not been paid

If it is a drug and it was manufactured, prepared, propagated, compounded, or processed in a facility for which fees have not been paid as required by section 744M.

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FFDCA § 503. Exemptions and consideration for certain drugs, devices, and biological products [21 U.S.C. § 353]

(a) Regulations for goods to be processed, labeled, or repacked elsewhere

The Secretary is directed to promulgate regulations exempting from any labeling or packaging requirement of this chapter drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

(b) Prescription by physician; exemption from labeling and prescription requirements; misbranded drugs; compliance with narcotic and marihuana laws

(1) A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug;

shall be dispensed only

(i) upon a written prescription of a practitioner licensed by law to administer such drug, or

(ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

(iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist.

The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

(2) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of section 502, except paragraphs (a), (i)(2) and (3), (k), and (l), and the packaging requirements of paragraphs (g), (h), and (p), if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of paragraph (1) of this subsection.

(3) The Secretary may by regulation remove drugs subject to section 505 from the requirements of paragraph (1) of this subsection when such requirements are not necessary for the protection of the public health.

(4)

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(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol "Rx only".

(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).

. . . .

(f) Veterinary prescription drugs

(1)

(A) A drug intended for use by animals other than man, other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug, which—

(i) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary for its use, is not safe for animal use except under the professional supervision of a licensed veterinarian, or

(ii) is limited by an approved application under subsection (b) of section 512, a conditionally-approved application under section 571, or an index listing under section 572 to use under the professional supervision of a licensed veterinarian,

shall be dispensed only by or upon the lawful written or oral order of a licensed veterinarian in the course of the veterinarian's professional practice.

(B) For purposes of subparagraph (A), an order is lawful if the order—

(i) is a prescription or other order authorized by law,

(ii) is, if an oral order, promptly reduced to writing by the person lawfully filling the order, and filed by that person, and

(iii) is refilled only if authorized in the original order or in a subsequent oral order promptly reduced to writing by the person lawfully filling the order, and filed by that person.

(C) The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

. . . .

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512, 571, or 572 from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

(4) A drug which is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the statement specified in the preceding sentence.

(g) Regulation of combination products

(1)

(A) The Secretary shall, in accordance with this subsection, assign a primary agency center to regulate products that constitute a combination of a drug, device, or biological product.

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(B) The Secretary shall conduct the premarket review of any combination product under a single application, whenever appropriate.

(C) For purposes of this subsection, the term "primary mode of action" means the single mode of action of a combination product expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

(D) The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(i) a drug (other than a biological product), the agency center charged with premarket review of drugs shall have primary jurisdiction;

(ii) a device, the agency center charged with premarket review of devices shall have primary jurisdiction; or

(iii) a biological product, the agency center charged with premarket review of biological products shall have primary jurisdiction.

(E) In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body.

(F) If a sponsor of a combination product disagrees with the determination under subparagraph (D)—

(i) such sponsor may request, and the Secretary shall provide, a substantive rationale to such sponsor that references scientific evidence provided by the sponsor and any other scientific evidence relied upon by the Secretary to support such determination . . . .

[the remainder of subsection (g), omitted here, sets out detailed requirements for processes applicable when a sponsor disagrees with FDA's determination relating to the primary mode of action of a combination product].

(h) Regulation of certain products as drugs

(1) Any contrast agent, radioactive drug, or OTC monograph drug shall be deemed to be a drug under section 201(g) and not a device under section 201(h).

(2) For purposes of this subsection:

(A) The term "contrast agent" means an article that is intended for use in conjunction with a medical imaging device, and—

(i) is a diagnostic radiopharmaceutical . . . ; or

(ii) is a diagnostic agent that improves the visualization of structure or function within the body by increasing the relative difference in signal intensity within the target tissue, structure, or fluid.

(B) The term "radioactive drug" has the meaning given such term in section 310.3(n) of title 21, Code of Federal Regulations (or any successor regulations), except that such term does not include—

(i) an implant or article similar to an implant;

(ii) an article that applies radiation from outside of the body; or

(iii) the radiation source of an article described in clause (i) or (ii).

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(C) The term ″OTC monograph drug″ has the meaning given such term in section 744L.

. . . .

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FFDCA § 503A. Pharmacy compounding [21 U.S.C. § 353a]

(a) In general

Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)

(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)

(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

. . . .

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because

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such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

. . . .

(c) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. . . .

(d) Application

This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 201(ii); or

(2) radiopharmaceuticals.

(e) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

. . . .

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FFDCA § 505. New drugs [21 U.S.C. § 355]

(a) Necessity of effective approval of application

No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug.

(b) Filing application; contents

(1)

(A) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such persons shall submit to the Secretary as part of the application—

(i) full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use;

(ii) a full list of the articles used as components of such drug;

(iii) a full statement of the composition of such drug;

(iv) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(v) such samples of such drug and of the articles used as components thereof as the Secretary may require;

(vi) specimens of the labeling proposed to be used for such drug;

(vii) any assessments required under section 505B; and

(viii) the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—

(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or

(II) claims a method of using such drug for which approval is sought or has been granted in the application.

(B) If an application is filed under this subsection for a drug, and a patent of the type described in subparagraph (A)(viii) is issued after the filing date but before approval of the application, the applicant shall amend the application to include the patent number and expiration date.

(2) An application submitted under paragraph (1) for a drug for which the investigations described in clause (A) of such paragraph and relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted shall also include—

(A) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the drug for which such investigations were conducted or which claims a use for such drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under paragraph (1) or subsection (c)—

(i) that such patent information has not been filed,

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(ii) that such patent has expired,

(iii) of the date on which such patent will expire, or

(iv) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(B) if with respect to the drug for which investigations described in paragraph (1)(A) were conducted information was filed under paragraph (1) or subsection (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

(3) Notice of opinion that patent is invalid or will not be infringed

(A) Agreement to give notice

An applicant that makes a certification described in paragraph (2)(A)(iv) shall include in the application a statement that the applicant will give notice as required by this paragraph.

. . . .

(D) Contents of notice

A notice required under this paragraph shall—

(i) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(ii) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

. . . .

(c) Period for approval of application; period for, notice, and expedition of hearing; period for issuance of order

(1) Within one hundred and eighty days after the filing of an application under subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(A) approve the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or

(B) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. . . .

(d) Grounds for refusing application; approval of application; "substantial evidence" defined

If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that

(1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

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(3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions; or

(5) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

(6) the application failed to contain the patent information prescribed by subsection (b); or

(7) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular;

he shall issue an order refusing to approve the application.

If, after such notice and opportunity for hearing, the Secretary finds that clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence. . . .

(e) Withdrawal of approval; grounds; immediate suspension upon finding imminent hazard to public health

The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds

(1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved;

(2) that new evidence of clinical experience, not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved; or

(3) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof; or

(4) the patent information prescribed by subsection (c) was not filed within thirty days after the receipt of written notice from the Secretary specifying the failure to file such information; or

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(5) that the application contains any untrue statement of a material fact:

Provided, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application submitted under subsection (b) or (j) with respect to any drug under this section if the Secretary finds

(1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports, in accordance with a regulation or order under subsection (k) or to comply with the notice requirements of section 510(k)(2), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or

(2) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

(3) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

Any order under this subsection shall state the findings upon which it is based. The Secretary may withdraw the approval of an application submitted under this section, or suspend the approval of such an application, as provided under this subsection, without first ordering the applicant to submit an assessment of the approved risk evaluation and mitigation strategy for the drug under section 505-1(g)(2)(D).

. . . .

(i) Exemptions of drugs for research; discretionary and mandatory conditions; direct reports to Secretary

(1) The Secretary shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. . . .

(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from nonclinical tests or human studies.

(3)

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(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish . . . .

(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible, it is contrary to the best interests of such human beings, or the proposed clinical testing poses no more than minimal risk to such human beings and includes appropriate safeguards as prescribed to protect the rights, safety, and welfare of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs. . . .

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)

(A) An abbreviated application for a new drug shall contain—

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)

(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active

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ingredient of a listed drug or of a drug which does not meet the requirements of section 201(p), and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (ii) through (vi) of subsection (b)(1)(A);

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c)—

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

. . . .

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(iv) Contents of notice

A notice required under this subparagraph shall—

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

. . . .

[the portion omitted here is large, and contains tremendously detailed statutory requirements on the conditions under which the Secretary can approve an abbreviated new drug application, the precise date on which such approval becomes effective, and the 180-exlusivitity period]

(7)

(A)

(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public—

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (c) respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(iv) For each drug included on the list, the Secretary shall specify any exclusivity period that is applicable, for which the Secretary has determined the expiration date, and for which such period has not yet expired . . . .

(s) Referral to advisory committee

Prior to the approval of a drug no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under this section or section 262 of Title 42, the Secretary shall—

(1) refer such drug to a Food and Drug Administration advisory committee for review at a meeting of such advisory committee; or

(2) if the Secretary does not refer such a drug to a Food and Drug Administration advisory committee prior to the approval of the drug, provide in the action letter on the application for the

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drug a summary of the reasons why the Secretary did not refer the drug to an advisory committee prior to approval.

. . . .

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FFDCA § 505-1. Risk evaluation and mitigation strategies [21 U.S.C. § 355-1]

(a) Submission of proposed strategy

(1) Initial approval

If the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, determines that a risk evaluation and mitigation strategy is necessary to ensure that the benefits of the drug outweigh the risks of the drug, and informs the person who submits such application of such determination, then such person shall submit to the Secretary as part of such application a proposed risk evaluation and mitigation strategy. In making such a determination, the Secretary shall consider the following factors:

(A) The estimated size of the population likely to use the drug involved.

(B) The seriousness of the disease or condition that is to be treated with the drug.

(C) The expected benefit of the drug with respect to such disease or condition.

(D) The expected or actual duration of treatment with the drug.

(E) The seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug.

(F) Whether the drug is a new molecular entity.

. . . .

(b) Definitions

. . . .

(c) Contents

A proposed risk evaluation and mitigation strategy under subsection (a) shall—

(1) include the timetable required under subsection (d); and

(2) to the extent required by the Secretary, in consultation with the office responsible for reviewing the drug and the office responsible for postapproval safety with respect to the drug, include additional elements described in subsections (e) and (f).

(d) Minimal strategy

For purposes of subsection (c)(1), the risk evaluation and mitigation strategy for a drug shall require a timetable for submission of assessments of the strategy . . . .

(e) Additional potential elements of strategy

(1) In general

The Secretary, in consultation with the offices described in subsection (c)(2), may under such subsection require that the risk evaluation and mitigation strategy for a drug include 1 or more of the additional elements described in this subsection if the Secretary makes the determination required with respect to each element involved.

(2) Medication Guide; patient package insert

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The risk evaluation and mitigation strategy for a drug may require that, as applicable, the responsible person develop for distribution to each patient when the drug is dispensed—

(A) a Medication Guide, as provided for under part 208 of title 21, Code of Federal Regulations (or any successor regulations); and

(B) a patient package insert, if the Secretary determines that such insert may help mitigate a serious risk of the drug.

(3) Communication plan

The risk evaluation and mitigation strategy for a drug may require that the responsible person conduct a communication plan to health care providers, if, with respect to such drug, the Secretary determines that such plan may support implementation of an element of the strategy (including under this paragraph). Such plan may include—

(A) sending letters to health care providers;

(B) disseminating information about the elements of the risk evaluation and mitigation strategy to encourage implementation by health care providers of components that apply to such health care providers, or to explain certain safety protocols (such as medical monitoring by periodic laboratory tests)[;]

(C) disseminating information to health care providers through professional societies about any serious risks of the drug and any protocol to assure safe use; or

(D) disseminating information to health care providers about drug formulations or properties, including information about the limitations or patient care implications of such formulations or properties, and how such formulations or properties may be related to serious adverse drug events associated with use of the drug.

(4) Packaging and disposal

The Secretary may require a risk evaluation mitigation strategy for a drug for which there is a serious risk of an adverse drug experience . . . which may include requiring that—

(A) the drug be made available for dispensing to certain patients in unit dose packaging, packaging that provides a set duration, or another packaging system that the Secretary determines may mitigate such serious risk; or

(B) the drug be dispensed to certain patients with a safe disposal packaging or safe disposal system if the Secretary determines that such safe disposal packaging or system may mitigate such serious risk and is sufficiently available.

(f) Providing safe access for patients to drugs with known serious risks that would otherwise be unavailable

(1) Allowing safe access to drugs with known serious risks

The Secretary, in consultation with the offices described in subsection (c)(2), may require that the risk evaluation and mitigation strategy for a drug include such elements as are necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if the Secretary determines that—

(A) the drug, which has been shown to be effective, but is associated with a serious adverse drug experience, can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug; and

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(B) for a drug initially approved without elements to assure safe use, other elements under subsections (c), (d), and (e) are not sufficient to mitigate such serious risk.

. . . .

(3) Elements to assure safe use

The elements to assure safe use under paragraph (1) shall include 1 or more goals to mitigate a specific serious risk listed in the labeling of the drug and, to mitigate such risk, may require that—

(A) health care providers who prescribe the drug have particular training or experience, or are specially certified (the opportunity to obtain such training or certification with respect to the drug shall be available to any willing provider from a frontier area in a widely available training or certification method (including an on-line course or via mail) as approved by the Secretary at reasonable cost to the provider);

(B) pharmacies, practitioners, or health care settings that dispense the drug are specially certified (the opportunity to obtain such certification shall be available to any willing provider from a frontier area);

(C) the drug be dispensed to patients only in certain health care settings, such as hospitals;

(D) the drug be dispensed to patients with evidence or other documentation of safe-use conditions, such as laboratory test results;

(E) each patient using the drug be subject to certain monitoring; or

(F) each patient using the drug be enrolled in a registry.

(4) Implementation system

The elements to assure safe use under paragraph (1) that are described in subparagraphs (B), (C), and (D) of paragraph (3) may include a system through which the applicant is able to take reasonable steps to—

(A) monitor and evaluate implementation of such elements by health care providers, pharmacists, and other parties in the health care system who are responsible for implementing such elements; and

(B) work to improve implementation of such elements by such persons.

. . . .

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FFDCA § 505G. Regulation of certain nonprescription drugs that are marketed without an approved drug application [21 U.S.C. § 355h]

(a) Nonprescription drugs marketed without an approved application

Nonprescription drugs marketed without an approved drug application under section 505, as of March 27, 2020, shall be treated in accordance with this subsection.

(1) Drugs subject to a final monograph; category I drugs subject to a tentative final monograph

A drug is deemed to be generally recognized as safe and effective under section 201(p)(1), not a new drug under section 201(p), and not subject to section 503(b)(1), if—

(A) the drug is—

(i) in conformity with the requirements for nonprescription use of a final monograph issued under part 330 of title 21, Code of Federal Regulations (except as provided in paragraph (2)), the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

(ii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 201(p)(2); or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a tentative final monograph that is the most recently applicable proposal or determination issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the proposed requirements for nonprescription use of such tentative final monograph, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsections (b), (c), and (k); and

(iii) except as permitted by an order issued under subsection (b) or, in the case of a minor change in the drug, in conformity with an order issued under subsection (c), in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 201(p)(2).

(2) Treatment of sunscreen drugs

With respect to sunscreen drugs subject to this section, the applicable requirements in terms of conformity with a final monograph, for purposes of paragraph (1)(A)(i), shall be the requirements specified in part 352 of title 21, Code of Federal Regulations, as published on May 21, 1999, beginning on page 27687 of volume 64 of the Federal Register, except that the applicable requirements governing effectiveness and labeling shall be those specified in section 201.327 of title 21, Code of Federal Regulations.

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(3) Category III drugs subject to a tentative final monograph; category I drugs subject to proposed monograph or advance notice of proposed rulemaking

A drug that is not described in paragraph (1), (2), or (4) is not required to be the subject of an application approved under section 505, and is not subject to section 503(b)(1), if—

(A) the drug is—

(i) classified in category III for safety or effectiveness in the preamble of a proposed rule establishing a tentative final monograph that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with—

(I) the conditions of use, including indication and dosage strength, if any, described for such category III drug in such preamble or in an applicable subsequent proposed rule;

(II) the proposed requirements for drugs classified in such tentative final monograph in category I in the most recently proposed rule establishing requirements related to such tentative final monograph and in any final rule establishing requirements that are applicable to the drug; and

(III) the general requirements for nonprescription drugs and conditions or requirements under subsection (b) or (k); and

(iii) in a dosage form that, immediately prior to March 27, 2020, had been used to a material extent and for a material time under section 201(p)(2); or

(B) the drug is—

(i) classified in category I for safety and effectiveness under a proposed monograph or advance notice of proposed rulemaking that is the most recently applicable proposal or determination for such drug issued under part 330 of title 21, Code of Federal Regulations;

(ii) in conformity with the requirements for nonprescription use of such proposed monograph or advance notice of proposed rulemaking, any applicable subsequent determination by the Secretary, the general requirements for nonprescription drugs, and conditions or requirements under subsection (b) or (k); and

(iii) in a dosage form that, immediately prior to March 27, 2020, has been used to a material extent and for a material time under section 201(p)(2).

(4) Category II drugs deemed new drugs

A drug that is classified in category II for safety or effectiveness under a tentative final monograph or that is subject to a determination to be not generally recognized as safe and effective in a proposed rule that is the most recently applicable proposal issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505 beginning on the day that is 180 calendar days after March 27, 2020, unless, before such day, the Secretary determines that it is in the interest of public health to extend the period during which the drug may be marketed without such an approved new drug application.

(5) Drugs not GRASE deemed new drugs

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A drug that the Secretary has determined not to be generally recognized as safe and effective under section 201(p)(1) under a final determination issued under part 330 of title 21, Code of Federal Regulations, shall be deemed to be a new drug under section 201(p), misbranded under section 502(ee), and subject to the requirement for an approved new drug application under section 505.

(6) Other drugs deemed new drugs

Except as provided in subsection (m), a drug is deemed to be a new drug under section 201(p) and misbranded under section 502(ee) if the drug—

(A) is not subject to section 503(b)(1); and

(B) is not described in paragraph (1), (2), (3), (4), or (5), or subsection (b)(1)(B).

(b) Administrative orders

[This subsection, omitted here, sets out in detail a process by which FDA can promulgate, modify, or repeal regulations relating to OTC drugs through an "administrative order" process. This process provides for some public notice, and some participation by interested parties, but is substantially less burdensome than notice-and-comment rulemaking.]

. . . .

(c) Procedure for minor changes

. . . .

(d) Confidentiality of information submitted to the Secretary

. . . .

(f) Approvals under section 505

The provisions of this section shall not be construed to preclude a person from seeking or maintaining the approval of an application for a drug under sections 505(b)(1), 505(b)(2), and 505(j). A determination under this section that a drug is not subject to section 503(b)(1), is generally recognized as safe and effective under section 201(p)(1), and is not a new drug under section 201(p) shall constitute a finding that the drug is safe and effective that may be relied upon for purposes of an application under section 505(b)(2), so that the applicant shall be required to submit for purposes of such application only information needed to support any modification of the drug that is not covered by such determination under this section.

(g) Public availability of administrative orders

The Secretary shall establish, maintain, update (as determined necessary by the Secretary but no less frequently than annually), and make publicly available, with respect to orders issued under this section—

(1) a repository of each final order and interim final order in effect, including the complete text of the order; and

(2) a listing of all orders proposed and under development under subsection (b)(2), including—

(A) a brief description of each such order; and

(B) the Secretary's expectations, if resources permit, for issuance of proposed orders over a 3-year period.

(h) Development advice to sponsors or requestors

The Secretary shall establish procedures under which sponsors or requestors may meet with appropriate officials of the Food and Drug Administration to obtain advice on the studies and other information

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necessary to support submissions under this section and other matters relevant to the regulation of nonprescription drugs and the development of new nonprescription drugs under this section.

(i) Participation of multiple sponsors or requestors

The Secretary shall establish procedures to facilitate efficient participation by multiple sponsors or requestors in proceedings under this section, including provision for joint meetings with multiple sponsors or requestors or with organizations nominated by sponsors or requestors to represent their interests in a proceeding.

. . . .

(k) Effect on existing regulations governing nonprescription drugs

(1) Regulations of general applicability to nonprescription drugs

Except as provided in this subsection, nothing in this section supersedes regulations establishing general requirements for nonprescription drugs, including regulations of general applicability contained in parts 201, 250, and 330 of title 21, Code of Federal Regulations, or any successor regulations. The Secretary shall establish or modify such regulations by means of rulemaking in accordance with section 553 of Title 5.

(2) Regulations establishing requirements for specific nonprescription drugs

(A) The provisions of section 310.545 of title 21, Code of Federal Regulations, as in effect on the day before March 27, 2020, shall be deemed to be a final order under subsection (b).

(B) Regulations in effect on the day before March 27, 2020, establishing requirements for specific nonprescription drugs marketed pursuant to this section (including such requirements in parts 201 and 250 of title 21, Code of Federal Regulations), shall be deemed to be final orders under subsection (b), only as they apply to drugs—

(i) subject to paragraph (1), (2), (3), or (4) of subsection (a); or

(ii) otherwise subject to an order under this section.

(3) Withdrawal of regulations

The Secretary shall withdraw regulations establishing final monographs and the procedures governing the over-the-counter drug review under part 330 and other relevant parts of title 21, Code of Federal Regulations (as in effect on the day before March 27, 2020), or make technical changes to such regulations to ensure conformity with appropriate terminology and cross references. Notwithstanding subchapter II of chapter 5 of Title 5, any such withdrawal or technical changes shall be made without public notice and comment and shall be effective upon publication through notice in the Federal Register (or upon such date as specified in such notice).

(l) Guidance

The Secretary shall issue guidance that specifies—

(1) the procedures and principles for formal meetings between the Secretary and sponsors or requestors for drugs subject to this section;

(2) the format and content of data submissions to the Secretary under this section;

(3) the format of electronic submissions to the Secretary under this section;

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(4) consolidated proceedings for appeal and the procedures for such proceedings where appropriate; and

(5) for minor changes in drugs, recommendations on how to comply with the requirements in orders issued under subsection (c)(3).

(m) Rule of construction

(1) In general

This section shall not affect the treatment or status of a nonprescription drug—

(A) that is marketed without an application approved under section 505 as of March 27, 2020;

(B) that is not subject to an order issued under this section; and

(C) to which paragraph (1), (2), (3), (4), or (5) of subsection (a) do not apply.

(2) Treatment of products previously found to be subject to time and extent requirements

(A) Notwithstanding subsection (a), a drug described in subparagraph (B) may only be lawfully marketed, without an application approved under section 505, pursuant to an order issued under this section.

(B) A drug described in this subparagraph is a drug which, prior to March 27, 2020, the Secretary determined in a proposed or final rule to be ineligible for review under the OTC drug review (as such phrase "OTC drug review" was used in section 330.14 of title 21, Code of Federal Regulations, as in effect on the day before March 27, 2020).

(3) Preservation of authority

(A) Nothing in paragraph (1) shall be construed to preclude or limit the applicability of any provision of this chapter other than this section.

(B) Nothing in subsection (a) shall be construed to prohibit the Secretary from issuing an order under this section finding a drug to be not generally recognized as safe and effective under section 201(p)(1), as the Secretary determines appropriate.

(n) Investigational new drugs

A drug is not subject to this section if an exemption for investigational use under section 505(i) is in effect for such drug.

. . . .

(p) Inapplicability of notice and comment rulemaking and other requirements

The requirements of subsection (b) shall apply with respect to orders issued under this section instead of the requirements of subchapter II of chapter 5 of Title 5.

(q) Definitions

In this section:

(1) The term "nonprescription drug" refers to a drug not subject to the requirements of section 503(b)(1).

(2) The term "sponsor" refers to any person marketing, manufacturing, or processing a drug that—

(A) is listed pursuant to section 510(j); and

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(B) is or will be subject to an administrative order under this section of the Food and Drug Administration.

(3) The term "requestor" refers to any person or group of persons marketing, manufacturing, processing, or developing a drug.

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FFDCA § 506. Expedited approval of drugs for serious or life-threatening diseases or conditions [21 U.S.C. § 356]

(a) Designation of a drug as a breakthrough therapy

(1) In general

The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a "breakthrough therapy".)

(2) Request for designation

The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) Designation

(A) In general

Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

(B) Actions

The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

(i) holding meetings with the sponsor and the review team throughout the development of the drug;

(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.

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(b) Designation of drug as fast track product

(1) In general

The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition, or if the Secretary designates the drug as a qualified infectious disease product under section 505f(d). (In this section, such a drug is referred to as a "fast track product".)

(2) Request for designation

The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(3) Designation

Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

(c) Accelerated approval of a drug for a serious or life-threatening disease or condition, including a fast track product

(1) In general

(A) Accelerated approval

The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. The approval described in the preceding sentence is referred to in this section as "accelerated approval".

(B) Evidence

The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic, pharmacologic, or other evidence developed using biomarkers, for example, or other scientific methods or tools.

(2) Limitation

(A) In general

Approval of a product under this subsection may be subject to 1 or both of the following requirements:

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(i) That the sponsor conduct an appropriate postapproval study or studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

(ii) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

(B) Studies not required

If the Secretary does not require that the sponsor of a product approved under accelerated approval conduct a postapproval study under this paragraph, the Secretary shall publish on the website of the Food and Drug Administration the rationale for why such study is not appropriate or necessary.

C) Postapproval study conditions.

Not later than the date of approval of a product under accelerated approval, the Secretary shall specify the conditions for a postapproval study or studies required to be conducted under this paragraph with respect to such product, which may include enrollment targets, the study protocol, and milestones, including the target date of study completion.

. . . .

(3) Expedited withdrawal of approval

(A) In general

The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures described in subparagraph (B) if—

(i) the sponsor fails to conduct any required postapproval study of the product with due diligence, including with respect to conditions specified by the Secretary under paragraph (2)(C);

(ii) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

(iii) other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; or

(iv) the sponsor disseminates false or misleading promotional materials with respect to the product.

(B) Expedited procedures described

. . . .

(d) Review of incomplete applications for approval of a fast track product

(1) In general

If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

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(A) provides a schedule for submission of information necessary to make the application complete; and

(B) pays any fee that may be required under section 736.

(2) Exception

Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

(e) Construction

(1) Purpose

The amendments made by the Food and Drug Administration Safety and Innovation Act and the 21st Century Cures Act to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

(2) Construction

Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).

. . . .

(g) Regenerative advanced therapy

(1) In general

The Secretary, at the request of the sponsor of a drug, shall facilitate an efficient development program for, and expedite review of, such drug if the drug qualifies as a regenerative advanced therapy under the criteria described in paragraph (2).

(2) Criteria

A drug is eligible for designation as a regenerative advanced therapy under this subsection if—

(A) the drug is a regenerative medicine therapy (as defined in paragraph (8));

(B) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and

(C) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition.

(3) Request for designation

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The sponsor of a drug may request the Secretary to designate the drug as a regenerative advanced therapy concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(4) Designation

Not later than 60 calendar days after the receipt of a request under paragraph (3), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (2). If the Secretary determines that the drug meets the criteria, the Secretary shall designate the drug as a regenerative advanced therapy and shall take such actions as are appropriate under paragraph (1). If the Secretary determines that a drug does not meet the criteria for such designation, the Secretary shall include with the determination a written description of the rationale for such determination.

(5) Actions

The sponsor of a regenerative advanced therapy shall be eligible for the actions to expedite development and review of such therapy under subsection (a)(3)(B), including early interactions to discuss any potential surrogate or intermediate endpoint to be used to support the accelerated approval of an application for the product under subsection (c).

(6) Access to expedited approval pathways

An application for a regenerative advanced therapy under section 505(b)(1) or section 351(a) of the Public Health Service Act may be—

(A) eligible for priority review, as described in the Manual of Policies and Procedures of the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012; and

(B) eligible for accelerated approval under subsection (c), as agreed upon pursuant to subsection (a)(3)(B), through, as appropriate—

(i) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit; or

(ii) reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites, as appropriate.

(7) Postapproval requirements

The sponsor of a regenerative advanced therapy that is granted accelerated approval and is subject to the postapproval requirements under subsection (c) may, as appropriate, fulfill such requirements, as the Secretary may require, through—

(A) the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records;

(B) the collection of larger confirmatory data sets, as agreed upon pursuant to subsection (a)(3)(B); or

(C) postapproval monitoring of all patients treated with such therapy prior to approval of the therapy.

(8) Definition

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For purposes of this section, the term "regenerative medicine therapy" includes cell therapy, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products, except for those regulated solely under section 361 of the Public Health Service Act and part 1271 of title 21, Code of Federal Regulations.

(h) Limited population pathway for antibacterial and antifungal drugs

(1) In general

The Secretary may approve an antibacterial or antifungal drug, alone or in combination with one or more other drugs, as a limited population drug pursuant to this subsection only if—

(A) the drug is intended to treat a serious or life-threatening infection in a limited population of patients with unmet needs;

(B) the standards for approval under section 505(c) and (d), or the standards for licensure under section 351 of the Public Health Service Act, as applicable, are met; and

(C) the Secretary receives a written request from the sponsor to approve the drug as a limited population drug pursuant to this subsection.

(2) Benefit-risk consideration

The Secretary's determination of safety and effectiveness of an antibacterial or antifungal drug shall reflect the benefit-risk profile of such drug in the intended limited population, taking into account the severity, rarity, or prevalence of the infection the drug is intended to treat and the availability or lack of alternative treatment in such limited population. Such drug may be approved under this subsection notwithstanding a lack of evidence to fully establish a favorable benefit-risk profile in a population that is broader than the intended limited population.

. . . .

(B) Promotional material

The sponsor of an antibacterial or antifungal drug subject to this subsection shall submit to the Secretary copies of all promotional materials related to such drug at least 30 calendar days prior to dissemination of the materials.

(4) Other programs

A sponsor of a drug that seeks approval of a drug under this subsection may also seek designation or approval, as applicable, of such drug under other applicable sections or subsections of this chapter or the Public Health Service Act.

(5) Guidance

. . . the Secretary shall issue draft guidance describing criteria, processes, and other general considerations for demonstrating the safety and effectiveness of limited population antibacterial and antifungal drugs. . . .

(6) Advice

The Secretary shall provide prompt advice to the sponsor of a drug for which the sponsor seeks approval under this subsection to enable the sponsor to plan a development program to obtain the necessary data for such approval, and to conduct any additional studies that would be required to gain approval of such drug for use in a broader population.

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(7) Termination of limitations

If, after approval of a drug under this subsection, the Secretary approves a broader indication for such drug under section 505(b) or section 351(a) of the Public Health Service Act, the Secretary may remove any postmarketing conditions, including requirements with respect to labeling and review of promotional materials under paragraph (3), applicable to the approval of the drug under this subsection.

. . . .

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FFDCA § 510. Registration of producers of drugs or devices [21 U.S.C. § 360]

(a) Definitions

As used in this section—

(1) the term "manufacture, preparation, propagation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

. . . .

(b) Annual registration

(1) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary . . . .

(2) During the period beginning on October 1 and ending on December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a device or devices shall register with the Secretary . . . .

(c) New producers

Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary—

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2).[]

(d) Additional establishments

Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices.

(e) Registration number; uniform system for identification of devices intended for human use

The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. . . .. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use . . . .

(f) Availability of registrations for inspection

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section . . . .

(g) Exclusions from application of section

The foregoing subsections of this section shall not apply to—

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(1) pharmacies which maintain establishments in conformance with any applicable local laws . . . and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(2) practitioners licensed by law to prescribe or administer drugs or devices and who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs or devices solely for use in research, teaching, or chemical analysis and not for sale;

(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or

(5) such other classes of persons as the Secretary may by regulation exempt from the application of this section . . . .

(h) Inspections

(1) In general

Every establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

(2) Risk-based schedule for devices

(A) In general

The Secretary. . . shall inspect establishments described in paragraph (1) that are engaged in the manufacture, propagation, compounding, or processing of a device or devices (referred to in this subsection as "device establishments") in accordance with a risk-based schedule . . . .

(B) Factors and considerations

In establishing the risk-based schedule under subparagraph (A), the Secretary shall—

(i) apply, to the extent applicable for device establishments, the factors identified in paragraph (4); and

(ii) consider the participation of the device establishment, as applicable, in international device audit programs in which the United States participates or the United States recognizes for purposes of inspecting device establishments.

(3) Risk-based schedule for drugs

The Secretary, acting through one or more officers or employees duly designated by the Secretary, shall inspect establishments described in paragraph (1) that are engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs (referred to in this subsection as "drug establishments") in accordance with a risk-based schedule . . . .

(5) Effect of status

In determining the risk associated with an establishment for purposes of establishing a risk-based schedule under paragraph (3), the Secretary shall not consider whether the drugs manufactured, prepared, propagated, compounded, or processed by such establishment are drugs described in section 503(b) .

(6) Annual report on inspections of establishments

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Beginning in 2014, not later than May 1 of each year, the Secretary shall make available on the Internet Web site of the Food and Drug Administration a report regarding—

(A)

(i) the number of domestic and foreign establishments registered pursuant to this section in the previous calendar year; and

(ii) the number of such domestic establishments and the number of such foreign establishments that the Secretary inspected in the previous calendar year;

(B) with respect to establishments that manufacture, prepare, propagate, compound, or process an active ingredient of a drug or a finished drug product, the number of each such type of establishment; and

(C) the percentage of the budget of the Food and Drug Administration used to fund the inspections described under subparagraph (A).

(i) Registration of foreign establishments

(1) Every person who owns or operates any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device that is imported or offered for import into the United States shall, through electronic means in accordance with the criteria of the Secretary—

(A) upon first engaging in any such activity, immediately submit a registration to the Secretary . . . .

(B) each establishment subject to the requirements of subparagraph (A) shall thereafter register with the Secretary during the period beginning on October 1 and ending on December 31 of each year.

(2) The establishment shall also provide the information required by subsection (j).

(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a) .

. . . .

(j) Filing of lists of drugs and devices manufactured, prepared, propagated and compounded by registrants; statements; accompanying disclosures

(1) Every person who registers with the Secretary under subsection (b), (c), (d), or (i) shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs and a list of all devices . . . which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution and which he has not included in any list of drugs or devices filed by him with the Secretary . . . before such time of registration. . . .

(2) Each person who registers with the Secretary under this section shall report to the Secretary, with regard to drugs once during the month of June of each year and once during the month of December of each year, and with regard to devices once each year during the period beginning on October 1 and ending on December 31, the following information:

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(A) A list of each drug or device introduced by the registrant for commercial distribution which has not been included in any list previously filed by him with the Secretary . . . .

(B) If since the date the registrant last made a report under this paragraph . . . he has discontinued the manufacture, preparation, propagation, compounding, or processing for commercial distribution of a drug or device included in a list filed by him . . . ; notice of such discontinuance, the date of such discontinuance, and the identity . . . of such drug or device.

(C) If since the date the registrant reported pursuant to subparagraph (B) a notice of discontinuance he has resumed the manufacture, preparation, propagation, compounding, or processing for commercial distribution of the drug or device with respect to which such notice of discontinuance was reported; notice of such resumption, the date of such resumption, the identity of such drug or device . . . .

(D) Any material change in any information previously submitted pursuant to this paragraph or paragraph (1).

. . . .

(4) The Secretary may also require each registrant under this section to submit a list of each drug product which

(A) the registrant is manufacturing, preparing, propagating, compounding, or processing for commercial distribution, and

(B) contains a particular ingredient.

The Secretary may not require the submission of such a list unless he has made a finding that the submission of such a list is necessary to carry out the purposes of this Act.

(5) The Secretary shall require persons subject to this subsection to use, for purposes of this subsection, the unique facility identifier systems specified under subsections (b)(3) and (i)(4) with respect to drugs. Such requirement shall not apply until the date that the identifier system under subsection (b)(3) or (i)(4), as applicable, is specified by the Secretary.

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 523(a) (in such form and manner as the Secretary shall by regulation prescribe)—

(1) the class in which the device is classified under section 513 or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 514 or 515 which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 402(j)(1) of the Public Health Service Act) shall be accompanied by the certification required under section 402(j)(5)(B) of such Act. Such certification shall not be considered an element of such notification.

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(l) Exemption from reporting requirements

(1) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513, or with respect to a change that is consistent with a predetermined change control plan cleared under section 515C. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

(2) Not later than 120 calendar days after December 13, 2016, and at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the Federal Register, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Upon such publication—

(A) each type of class I device so identified shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(m) List of exempt class II devices; initial and final determinations by Secretary; publication in Federal Register

(1) The Secretary shall—

(A) not later than 90 days after December 13, 2016, and at least once every 5 years thereafter, as the Secretary determines appropriate—

(i) publish in the Federal Register a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness; and

(ii) provide for a period of not less than 60 calendar days for public comment beginning on the date of the publication of such notice; and

(B) not later than 210 calendar days after December 13, 2016, publish in the Federal Register a list representing the Secretary's final determination with respect to the devices contained in the list published under subparagraph (A).

(2) Beginning on the date that is 1 calendar day after the date of publication of the final list under paragraph (1)(B), the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 60-calendar-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.

(3) Upon the publication of the final list under paragraph (1)(B)—

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(A) each type of class II device so listed shall be exempt from the requirement for a report under subsection (k); and

(B) the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

(n) Review of report; time for determination by Secretary

(1) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.

(2)

(A) Not later than 18 months after July 9, 2012, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report regarding when a premarket notification under subsection (k) should be submitted for a modification or change to a legally marketed device. The report shall include the Secretary's interpretation of the following terms: "could significantly affect the safety or effectiveness of the device", "a significant change or modification in design, material, chemical composition, energy source, or manufacturing process", and "major change or modification in the intended use of the device". The report also shall discuss possible processes for industry to use to determine whether a new submission under subsection (k) is required and shall analyze how to leverage existing quality system requirements to reduce premarket burden, facilitate continual device improvement, and provide reasonable assurance of safety and effectiveness of modified devices. In developing such report, the Secretary shall consider the input of interested stakeholders.

(B) The Secretary shall withdraw the Food and Drug Administration draft guidance entitled "Guidance for Industry and FDA Staff—510(k) Device Modifications: Deciding When to Submit a 510(k) for a Change to an Existing Device", dated July 27, 2011, and shall not use this draft guidance as part of, or for the basis of, any premarket review or any compliance or enforcement decisions or actions. The Secretary shall not issue—

(i) any draft guidance or proposed regulation that addresses when to submit a premarket notification submission for changes and modifications made to a manufacturer's previously cleared device before the receipt by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate of the report required in subparagraph (A); and

(ii) any final guidance or regulation on that topic for one year after date of receipt of such report by the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(C) The Food and Drug Administration guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device", dated January 10, 1997, shall be in effect until the subsequent issuance of guidance or promulgation, if appropriate, of a regulation described in subparagraph (B), and the Secretary shall interpret such guidance in a manner that is consistent with the manner in which the Secretary has interpreted such guidance since 1997.

. . . .

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FFDCA § 512. New animal drugs [21 U.S.C. § 360b]

(a) Unsafe new animal drugs and animal feed containing such drugs; conditions of safety; exemption of drugs for research; import tolerances

(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of section 501(a)(5) and section 402(a)(2)(C)(ii) unless—

(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such approved application;

(B) there is in effect a conditional approval of an application filed pursuant to section 571 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such conditionally approved application;

(C) there is in effect an index listing pursuant to section 572 with respect to such use or intended use of such drug in a minor species, and such drug, its labeling, and such use conform to such index listing; or

(D) there is in effect an authorization pursuant to section 564 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to any conditions of such authorization.

. . . .

(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed be deemed unsafe for purposes of section 501(a)(6) unless—

(A) there is in effect—

(i) an approval of an application filed pursuant to subsection (b) with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such approved application;

(ii) a conditional approval of an application filed pursuant to section 571 with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such conditionally approved application; or

(iii) an index listing pursuant to section 572 with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such index listing; and

(B) such animal feed is manufactured at a site for which there is in effect a license issued pursuant to subsection (m)(1) to manufacture such animal feed.

(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 501(a)(5) or (6) if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under subsection (j).

(4)

(A) Except as provided in subparagraph (B), if an approval of an application filed under subsection (b) is in effect with respect to a particular use or intended use of a new animal drug, the drug shall not be deemed unsafe for the purposes of paragraph (1) and shall be exempt from the requirements

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of 502(f) with respect to a different use or intended use of the drug, other than a use in or on animal feed, if such use or intended use—

(i) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(ii) is in compliance with regulations promulgated by the Secretary that establish the conditions for such different use or intended use.

The regulations promulgated by the Secretary under clause (ii) may prohibit particular uses of an animal drug and shall not permit such different use of an animal drug if the labeling of another animal drug that contains the same active ingredient and which is in the same dosage form and concentration provides for such different use.

. . . .

(5) If the approval of an application filed under section 505 is in effect, the drug under such application shall not be deemed unsafe for purposes of paragraph (1) and shall be exempt from the requirements of section 502(f) with respect to a use or intended use of the drug in animals if such use or intended use—

(A) is by or on the lawful written or oral order of a licensed veterinarian within the context of a veterinarian-client-patient relationship, as defined by the Secretary; and

(B) is in compliance with regulations promulgated by the Secretary that establish the conditions for the use or intended use of the drug in animals.

. . . .

(b) Filing application for uses of new animal drug; contents; patent information; abbreviated application; presubmission conference

(1) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application

(A) full reports of investigations which have been made to show whether or not such drug is safe and effective for use;

(B) a full list of the articles used as components of such drug;

(C) a full statement of the composition of such drug;

(D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(E) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require;

(F) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant;

(G) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and

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(H) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

The applicant shall file with the application the patent number and the expiration date of any patent which claims the new animal drug for which the applicant filed the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.

. . . .

(2) Any person may file with the Secretary an abbreviated application for the approval of a new animal drug. An abbreviated application shall contain the information required by subsection (n).

. . . .

(c) Period for submission and approval of application; period for notice and expedition of hearing; period for issuance of order; abbreviated applications; withdrawal periods; effective date of approval; relationship to other applications; withdrawal or suspension of approval; bioequivalence; filing of additional patent information

. . . .

(d) Grounds for refusing application; approval of application; factors; "substantial evidence" defined; combination drugs

(1) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that—

(A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

(B) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

(C) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity;

(D) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

(E) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(F) upon the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will result in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;

(G) the application failed to contain the patent information prescribed by subsection (b)(1);

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(H) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

(I) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice

(i) such drug will not adversely affect the animals for which it is intended, and

(ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (I) do not apply, he shall issue an order approving the application.

(2) In determining whether such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Secretary shall consider, among other relevant factors,

(A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug,

(B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance,

(C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and

(D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice.

Any order issued under this subsection refusing to approve an application shall state the findings upon which it is based.

(3) As used in this section, the term "substantial evidence" means evidence consisting of one or more adequate and well controlled investigations, such as—

(A) a study in a target species;

(B) a study in laboratory animals;

(C) any field investigation that may be required under this section and that meets the requirements of subsection (b)(3) if a presubmission conference is requested by the applicant;

(D) a bioequivalence study; or

(E) an in vitro study;

by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the

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drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

. . . .

(5) In reviewing an application that proposes a change to add an intended use for a minor use or a minor species to an approved new animal drug application, the Secretary shall reevaluate only the relevant information in the approved application to determine whether the application for the minor use or minor species can be approved. A decision to approve the application for the minor use or minor species is not, implicitly or explicitly, a reaffirmation of the approval of the original application.

. . . .

(j) Exemption of drugs for research; discretionary and mandatory conditions

To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this section new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. Such regulations may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable him to evaluate the safety and effectiveness of such article in the event of the filing of an application pursuant to this section. Such regulations, among other things, shall set forth the conditions (if any) upon which animals treated with such articles, and any products of such animals (before or after slaughter), may be marketed for food use.

. . . .

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FFDCA 512A. Priority Zoonotic Animal Drugs [21 U.S.C. § 360b-1]

(a) In general

The Secretary shall, at the request of the sponsor intending to submit an application for approval of a new animal drug under section 512(b)(1) or an application for conditional approval of a new animal drug under section 517, expedite the development and review of such new animal drug if preliminary clinical evidence indicates that the new animal drug, alone or in combination with 1 or more other animal drugs, has the potential to prevent or treat a zoonotic disease in animals, including a vector borne-disease, that has the potential to cause serious adverse health consequences for, or serious or life-threatening diseases in, humans.

(b) Request for designation

The sponsor of a new animal drug may request the Secretary to designate a new animal drug described in subsection (a) as a priority zoonotic animal drug. A request for the designation may be made concurrently with, or at any time after, the opening of an investigational new animal drug file under section 512(j) or the filing of an application under 512(b)(1) or 571.

(c) Designation

(1) In general

Not later than 60 calendar days after the receipt of a request under subsection (b), the Secretary shall determine whether the new animal drug that is the subject of the request meets the criteria described in subsection (a). If the Secretary determines that the new animal drug meets the criteria, the Secretary shall designate the new animal drug as a priority zoonotic animal drug and shall take such actions as are appropriate to expedite the development and review of the application for approval or conditional approval of such new animal drug.

(2) Actions

The actions to expedite the development and review of an application under paragraph (1) may include, as appropriate—

(A) taking steps to ensure that the design of clinical trials is as efficient as practicable, when scientifically appropriate, such as by utilizing novel trial designs or drug development tools (including biomarkers) that may reduce the number of animals needed for studies;

(B) providing timely advice to, and interactive communication with, the sponsor (which may include meetings with the sponsor and review team) regarding the development of the new animal drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable;

(C) involving senior managers and review staff with experience in zoonotic or vector-borne disease to facilitate collaborative, cross-disciplinary review, including, as appropriate, across agency centers; and

(D) implementing additional administrative or process enhancements, as necessary, to facilitate an efficient review and development program.

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FFDCA § 513. Classification of devices intended for human use [21 U.S.C. § 360c]

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) Class I, general controls—

(i) A device for which the controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 or any combination of such sections are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury,

is to be regulated by the controls referred to in clause (i).

(B) Class II, special controls—

A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) Class III, premarket approval—

A device which because—

(i) it

(I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and

(II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

(ii)

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(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or

(II) presents a potential unreasonable risk of illness or injury,

is to be subject, in accordance with section 515, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

(2) For purposes of this section and sections 514 and 515, the safety and effectiveness of a device are to be determined—

(A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

(3)

(A) Except as authorized by subparagraph (B), the effectiveness of a device is, for purposes of this section and sections 514 and 515, to be determined, in accordance with regulations promulgated by the Secretary, on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate, by experts qualified by training and experience to evaluate the effectiveness of the device, from which investigations it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device.

(B) If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A))—

(i) which is sufficient to determine the effectiveness of a device, and

(ii) from which it can fairly and responsibly be concluded by qualified experts that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device,

then, for purposes of this section and sections 514 and 515, the Secretary may authorize the effectiveness of the device to be determined on the basis of such evidence.

(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

(D)

(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to

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demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

(iii) For purposes of clause (ii), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides reasonable assurance of the effectiveness of the device.

(iv) Nothing in this subparagraph shall alter the criteria for evaluating an application for premarket approval of a device.

(v) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.

. . . .

(b) Classification panels

. . . .

(c) Classification panel organization and operation

. . . .

(d) Panel recommendation; publication; priorities

(1) Upon receipt of a recommendation from a panel respecting a device, the Secretary shall publish in the Federal Register the panel's recommendation and a proposed regulation classifying such device and shall provide interested persons an opportunity to submit comments on such recommendation and the proposed regulation. After reviewing such comments, the Secretary shall, subject to paragraph (2), by regulation classify such device.

(2)

(A) A regulation under paragraph (1) classifying a device in class I shall prescribe which, if any, of the requirements of section 510, 519, or 520(f) shall not apply to the device. A regulation which makes a requirement of section 510, 519, or 520(f) inapplicable to a device shall be accompanied by a statement of the reasons of the Secretary for making such requirement inapplicable.

(B) A device described in subsection (c)(2)(C) of this section shall be classified in class III unless the Secretary determines that classification of the device in such class is not necessary to provide

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reasonable assurance of its safety and effectiveness. A proposed regulation under paragraph (1) classifying such a device in a class other than class III shall be accompanied by a full statement of the reasons of the Secretary (and supporting documentation and data) for not classifying such device in such class and an identification of the risks to health (if any) presented by such device.

. . . .

(e) Classification changes

(1)

(A)

(i) Based on new information respecting a device, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, change the classification of such device, and revoke, on account of the change in classification, any regulation or requirement in effect under section 514 or 515 with respect to such device, by administrative order published in the Federal Register following publication of a proposed reclassification order in the Federal Register, a meeting of a device classification panel described in subsection (b), and consideration of comments to a public docket, notwithstanding subchapter II of chapter 5 of Title 5. The proposed reclassification order published in the Federal Register shall set forth the proposed reclassification, and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including—

(I) the public health benefit of the use of the device, and the nature and, if known, incidence of the risk of the device;

(II) in the case of a reclassification from class II to class III, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are not sufficient to provide a reasonable assurance of safety and effectiveness for such device; and

(III) in the case of reclassification from class III to class II, why general controls pursuant to subsection (a)(1)(A) and special controls pursuant to subsection (a)(1)(B) together are sufficient to provide a reasonable assurance of safety and effectiveness for such device.

(ii) An order under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 514 for such device.

(B) Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) By an order issued under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(f) Initial classification and reclassification of certain devices

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(1) Any device intended for human use which was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, is classified in class III unless—

(A) the device—

(i) is within a type of device

(I) which was introduced or delivered for introduction into interstate commerce for commercial distribution before such date and which is to be classified pursuant to subsection (b), or

(II) which was not so introduced or delivered before such date and has been classified in class I or II, and

(ii) is substantially equivalent to another device within such type;

(B) the Secretary in response to a petition submitted under paragraph (3) has classified such device in class I or II; or

(C) the device is classified pursuant to a request submitted under paragraph (2).

A device classified in class III under this paragraph shall be classified in that class until the effective date of an order of the Secretary under paragraph (2) or (3) classifying the device in class I or II.

(2)

(A)

(i) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this chapter, and that is classified into class III under paragraph (1), may request, after receiving written notice of such a classification, the Secretary to classify the device.

(ii) In lieu of submitting a report under section 510(k) and submitting a request for classification under clause (i) for a device, if a person determines there is no legally marketed device upon which to base a determination of substantial equivalence (as defined in subsection (i)), a person may submit a request under this clause for the Secretary to classify the device.

(iii) Upon receipt of a request under clause (i) or (ii), the Secretary shall classify the device subject to the request under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1) within 120 days.

(iv) Notwithstanding clause (iii), the Secretary may decline to undertake a classification request submitted under clause (ii) if the Secretary identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence under paragraph (1), or when the Secretary determines that the device submitted is not of low to moderate risk or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

(v) The person submitting the request for classification under this subparagraph may recommend to the Secretary a classification for the device and shall, if recommending classification in class II, include in the request an initial draft proposal for applicable special controls, as described in subsection (a)(1)(B), that are necessary, in conjunction with general controls, to provide reasonable assurance of safety and effectiveness and a description of how

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the special controls provide such assurance. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

(B)

(i) The Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.

. . . .

(4) If a manufacturer reports to the Secretary under section 510(k) that a device is substantially equivalent to another device—

(A) which the Secretary has classified as a class III device under subsection (b) of this section,

(B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(C) for which no final regulation requiring premarket approval has been promulgated under section 515(b),

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) report is being made and which has not been submitted to the Secretary under section 519. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

. . . .

(g) Information

Within sixty days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this chapter, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this chapter applicable to the device.

(h) Definitions

For purposes of this section and sections 501, 510, 514, 515, 516, 519, and 520

(1) a reference to "general controls" is a reference to the controls authorized by or under sections 501, 502, 510, 516, 518, 519, and 520,

(2) a reference to "class I", "class II", or "class III" is a reference to a class of medical devices described in subparagraph (A), (B), or (C) of subsection (a)(1) of this section, and

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(3) a reference to a "panel under section 513" is a reference to a panel established or authorized to be used under this section.

(i) Substantial equivalence

(1)

(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)

(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and

(II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

(D)

(i) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

(ii) For purposes of clause (i), the term "necessary" means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.

(iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

(E)

(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the "Director") may require a statement in labeling that provides appropriate

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information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

(II) that such use could cause harm.

(ii) Such determination shall—

(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

(II) specify the limitations on the use of the device not included in the proposed labeling; and

(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

(iii) The responsibilities of the Director under this subparagraph may not be delegated.

(F) Not later than 270 days after November 21, 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)

(A) As part of a submission under section 510(k) respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

. . . .

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FFDCA § 515. Premarket approval [21 U.S.C. § 360e]

(a) General requirement

A class III device—

(1) which is subject to an order issued under subsection (b) (or a regulation promulgated under such subsection prior to July 9, 2012); or

(2) which is a class III device because of section 513(f),

is required to have, unless exempt under section 520(g), an approval under this section of an application for premarket approval or, as applicable, an approval under subsection (c)(2) of this section of a report seeking premarket approval.

(b) Order to require premarket approval

(1) In the case of a class III device which—

(A) was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976; or

(B) is

(i) of a type so introduced or delivered, and

(ii) is substantially equivalent to another device within that type,

the Secretary shall by administrative order following publication of a proposed order in the Federal Register, a meeting of a device classification panel described in section 513(b), and consideration of comments from all affected stakeholders, including patients, payors, and providers, notwithstanding subchapter II of chapter 5 of Title 5, require that such device have an approval under this section of an application for premarket approval. Authority to issue such administrative order shall not be delegated below the Director of the Center for Devices and Radiological Health, acting in consultation with the Commissioner.

(2) A proposed order required under paragraph (1) shall contain—

(A) the proposed order;

(B) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved application for premarket approval and the benefit to the public from use of the device;

(C) opportunity for the submission of comments on the proposed order and the proposed findings; and

(D) opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

(3) After the expiration of the period for comment on a proposed order and proposed findings published under paragraph (2), consideration of comments submitted on such proposed order and findings, and a meeting of a device classification panel described in section 513(b), the Secretary shall

(A) issue an administrative order under paragraph (1) and publish in the Federal Register findings on the matters referred to in paragraph (2)(B), or

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(B) publish a notice terminating the proceeding for the issuance of the administrative order together with the reasons for such termination.

If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 516) initiate a proceeding under section 513(e) to reclassify the device subject to the proceeding terminated by such notice.

(c) Application for premarket approval

(1) Any person may file with the Secretary an application for premarket approval for a class III device. Such an application for a device shall contain—

(A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning the location of one or more such devices readily available for examination and testing;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 402(j)(5)(B) of the Public Health Service Act (which shall not be considered an element of such application); and

(H) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.

. . . .

(3) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 513,

refer such application to the appropriate panel under section 513 for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Where appropriate, the Secretary shall ensure that such panel includes, or consults with, one or more pediatric experts.

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. . . .

(5)

(A) In requesting additional information with respect to an application under this section, the Secretary shall consider the least burdensome appropriate means necessary to demonstrate a reasonable assurance of device safety and effectiveness.

(B) For purposes of subparagraph (A), the term "necessary" means the minimum required information that would support a determination by the Secretary that an application provides a reasonable assurance of the safety and effectiveness of the device.

(C) For purposes of this paragraph, the Secretary shall consider the role of postmarket information in determining the least burdensome means of demonstrating a reasonable assurance of device safety and effectiveness.

(D) Nothing in this paragraph alters the standards for premarket approval of a device.

(d) Action on application for premarket approval

(1)

(A) As promptly as possible, but in no event later than one hundred and eighty days after the receipt of an application under subsection (c) (except as provided in section 520(l)(3)(D)(ii) or unless, in accordance with subparagraph (B)(i), an additional period as agreed upon by the Secretary and the applicant), the Secretary, after considering the report and recommendation submitted under paragraph (2) of such subsection, shall—

(i) issue an order approving the application if he finds that none of the grounds for denying approval specified in paragraph (2) of this subsection applies; or

(ii) deny approval of the application if he finds (and sets forth the basis for such finding as part of or accompanying such denial) that one or more grounds for denial specified in paragraph (2) of this subsection apply.

In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

(B)

. . . .

(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c) of this section) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

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(II) the data or information relates to a device approved under this section, is available for use under this chapter, and is relevant to the design and intended use of the device for which the application is pending.

(2) The Secretary shall deny approval of an application for a device if, upon the basis of the information submitted to the Secretary as part of the application and any other information before him with respect to such device, the Secretary finds that—

(A) there is a lack of a showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(B) there is a lack of a showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

(C) the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the requirements of section 520(f);

(D) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(E) such device is not shown to conform in all respects to a performance standard in effect under section 514 compliance with which is a condition to approval of the application and there is a lack of adequate information to justify the deviation from such standard.

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to place such application in approvable form (which measures may include further research by the applicant in accordance with one or more protocols prescribed by the Secretary).

(3)

(A)

(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

(iii) The Secretary shall notify the applicant promptly of—

(I) any additional deficiency identified in the application, or

(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

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(4) An applicant whose application has been denied approval may, by petition filed on or before the thirtieth day after the date upon which he receives notice of such denial, obtain review thereof in accordance with either paragraph (1) or (2) of subsection (g) of this section, and any interested person may obtain review, in accordance with paragraph (1) or (2) of subsection (g), of an order of the Secretary approving an application.

(5)

(A)

(i) Unless the change is consistent with a predetermined change control plan approved under section 515C, a supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

(B)

(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a device that affects safety or effectiveness, the Secretary shall approve such supplement if—

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.

. . . .

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FFDCA § 515B. Breakthrough devices [21 U.S.C. § 360e-3]

(a) Purpose

The purpose of this section is to encourage the Secretary, and provide the Secretary with sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the Food and Drug Administration's review of, devices that represent breakthrough technologies.

(b) Establishment of program

The Secretary shall establish a program to expedite the development of, and provide for the priority review for, devices, as determined by the Secretary—

(1) that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

(2)

(A) that represent breakthrough technologies;

(B) for which no approved or cleared alternatives exist;

(C) that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or

(D) the availability of which is in the best interest of patients.

(c) Request for designation

A sponsor of a device may request that the Secretary designate such device for expedited development and priority review under this section. Any such request for designation may be made at any time prior to the submission of an application under section 515(c), a notification under section 510(k), or a petition for classification under section 513(f)(2).

(d) Designation process

(1) In general

Not later than 60 calendar days after the receipt of a request under subsection (c), the Secretary shall determine whether the device that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the device meets the criteria, the Secretary shall designate the device for expedited development and priority review.

(2) Review

Review of a request under subsection (c) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.

(3) Withdrawal

The Secretary may not withdraw a designation granted under this section on the basis of the criteria under subsection (b) no longer applying because of the subsequent clearance or approval of another device that—

(A) was designated under this section; or

(B) was given priority review under section 515(d)(5), as in effect prior to December 13, 2016.

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(e) Expedited development and priority review

(1) Actions

For purposes of expediting the development and review of devices designated under subsection (d) the Secretary shall—

(A) assign a team of staff, including a team leader with appropriate subject matter expertise and experience, for each device for which a request is submitted under subsection (c);

(B) provide for oversight of the team by senior agency personnel to facilitate the efficient development of the device and the efficient review of any submission described in subsection (c) for the device;

(C) adopt an efficient process for timely dispute resolution;

(D) provide for interactive and timely communication with the sponsor of the device during the development program and review process;

(E) expedite the Secretary's review of manufacturing and quality systems compliance, as applicable;

(F) disclose to the sponsor, not less than 5 business days in advance, the topics of any consultation the Secretary intends to undertake with external experts or an advisory committee concerning the sponsor's device and provide the sponsor the opportunity to recommend such external experts;

(G) provide for advisory committee input, as the Secretary determines appropriate (including in response to the request of the sponsor) for applications submitted under section 515(c); and

(H) assign staff to be available within a reasonable time to address questions by institutional review committees concerning the conditions and clinical testing requirements applicable to the investigational use of the device pursuant to an exemption under section 520(g).

(2) Additional actions

In addition to the actions described in paragraph (1), for purposes of expediting the development and review of devices designated under subsection (d), the Secretary, in collaboration with the device sponsor, may, as appropriate—

(A) coordinate with the sponsor regarding early agreement on a data development plan;

(B) take steps to ensure that the design of clinical trials is as efficient and flexible as practicable, when scientifically appropriate;

(C) facilitate, when scientifically appropriate, expedited and efficient development and review of the device through utilization of timely postmarket data collection with regard to application for approval under section 515(c); and

(D) agree in writing to clinical protocols that the Secretary will consider binding on the Secretary and the sponsor, subject to—

(i) changes to such protocols agreed to in writing by the sponsor and the Secretary; or

(ii) a decision, made by the director of the office responsible for reviewing the device submission, that a substantial scientific issue essential to determining the safety or effectiveness of such device exists, provided that such decision is in writing, and is made only after the Secretary provides to the device sponsor or applicant an opportunity for a meeting at

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which the director and the sponsor or applicant are present and at which the director documents the substantial scientific issue.

(f) Priority review guidance

(1) Content

. . . the Secretary shall issue guidance on the implementation of this section. Such guidance shall—

(A) set forth the process by which a person may seek a designation under subsection (d);

(B) provide a template for requests under subsection (c);

(C) identify the criteria the Secretary will use in evaluating a request for designation under this section; and

(D) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review devices designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

. . . .

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FFDCA § 520. General provisions respecting control of devices intended for human use [21 U.S.C. § 360j]

(a) General rule

Any requirement authorized by or under section 501, 502, 510, or 519 applicable to a device intended for human use shall apply to such device until the applicability of the requirement to the device has been changed by action taken under section 513, 514, or 515 or under subsection (g) of this section, and any requirement established by or under section 501, 502, 510, or 519 which is inconsistent with a requirement imposed on such device under section 514 or 515 or under subsection (g) of this section shall not apply to such device.

. . . .

(e) Restricted devices

(1) The Secretary may by regulation require that a device be restricted to sale, distribution, or use—

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation,

if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. . . .A device subject to a regulation under this subsection is a restricted device.

(2) The label of a restricted device shall bear such appropriate statements of the restrictions required by a regulation under paragraph (1) as the Secretary may in such regulation prescribe.

(f) Good manufacturing practice requirements

(1)

(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this Act.

(B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall—

(i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;

(ii) afford opportunity for an oral hearing; and

(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

(2)

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(A) Any person subject to any requirement prescribed by regulations under paragraph (1) may petition the Secretary for an exemption or variance from such requirement. Such a petition shall be submitted to the Secretary in such form and manner as he shall prescribe . . .

An order of the Secretary approving a petition for a variance shall prescribe such conditions respecting the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of the device to be granted the variance under the petition as may be necessary to assure that the device will be safe and effective and otherwise in compliance with this Act.

. . . .

(D) After the issuance of an order under subparagraph (B) respecting a petition, the petitioner shall have an opportunity for an informal hearing on such order.

(3) The Secretary shall establish an advisory committee for the purpose of advising and making recommendations to him with respect to regulations proposed to be promulgated under paragraph (1)(A) and the approval or disapproval of petitions submitted under paragraph (2). . . .

(g) Exemption for devices for investigational use

(1) It is the purpose of this subsection to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for human use and to that end to maintain optimum freedom for scientific investigators in their pursuit of that purpose.

(2)

(A) The Secretary shall. . . by regulation prescribe procedures and conditions under which devices intended for human use may upon application be granted an exemption from the requirements of section 502, 510, 514, 515, 516, 519, or 721 or subsection (e) or (f) of this section or from any combination of such requirements to permit the investigational use of such devices by experts qualified by scientific training and experience to investigate the safety and effectiveness of such devices.

(B) The conditions prescribed pursuant to subparagraph (A) shall include the following:

(i) A requirement that an application be submitted to the Secretary before an exemption may be granted and that the application be submitted in such form and manner as the Secretary shall specify.

(ii) A requirement that the person applying for an exemption for a device assure the establishment and maintenance of such records, and the making of such reports to the Secretary of safety or effectiveness data obtained as a result of the investigational use of the device during the exemption, as the Secretary determines will enable him to assure compliance with such conditions, review the progress of the investigation, and evaluate the safety and effectiveness of the device.

(iii) Such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety.

. . . .

(6)

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(A) . . . the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

(ii) changes or modifications to clinical protocols that do not affect—

(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

(III) the rights, safety, or welfare of the human subjects involved in the investigation.

(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

. . . .

(8)

(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a "clinical hold") if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is a determination that—

(i) the device involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the device, the design of the clinical investigation, the condition for which the device is to be investigated, and the health status of the subjects involved; or

(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish.

. . . .

(l) Transitional provisions for devices considered as new drugs

(1) Any device intended for human use—

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(A) for which on May 28, 1976 (hereinafter in this subsection referred to as the "enactment date") an approval of an application submitted under section 505(b) was in effect;

(B) for which such an application was filed on or before the enactment date and with respect to which application no order of approval or refusing to approve had been issued on such date under subsection (c) or (d) of such section;

(C) for which on the enactment date an exemption under subsection (i) of such section was in effect;

(D) which is within a type of device described in subparagraph (A), (B), or (C) and is substantially equivalent to another device within that type;

(E) which the Secretary in a notice published in the Federal Register before the enactment date has declared to be a new drug subject to section 505; or

(F) with respect to which on the enactment date an action is pending in a United States court under section 302, 303, or 304 for an alleged violation of a provision of section 301 which enforces a requirement of section 505 or for an alleged violation of section 505(a),

is classified in class III unless the Secretary in response to a petition submitted under paragraph (2) has classified such device in class I or II.

. . . .

(m) Humanitarian device exemption

(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect not more than 8,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 514 and 515 for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects not more than 8,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

The request shall be in the form of an application submitted to the Secretary and such application shall include the certification required under section 402(i)(5)(B) of the Public Health Services Act (which shall not be considered an element of such application). Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.

(3) Except as provided in paragraph (6), no person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

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(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities in which clinical testing of devices is supervised by an institutional review committee established in accordance with the regulations of the Secretary; and

(B) if, before the use of a device, an institutional review committee or an appropriate local committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A), unless a physician determines in an emergency situation that approval from an institutional review committee or an appropriate local committee can not be obtained in time to prevent serious harm or death to a patient.

In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee or an appropriate local committee, the physician shall, after the use of the device, notify the chairperson of the institutional review committee or an appropriate local committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

. . . .

(n) Regulation of contact lenses as devices

(1) All contact lenses shall be deemed to be devices under section 201(h).

(2) Paragraph (1) shall not be construed as bearing on or being relevant to the question of whether any product other than a contact lens is a device as defined by section 201(h) or a drug as defined by section 201(g).

(o) Regulation of medical and certain decisions support software

(1) The term [“]device[“], as defined in section 201(h), shall not include a software function that is intended—

(A) for administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;

(B) for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

(C) to serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—

(i) such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

(ii) such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

(iii) such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;

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(D) for transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings; or

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of—

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and

(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

(2) In the case of a product with multiple functions that contains—

(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and

(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

the Secretary shall not regulate the software function of such product described in subparagraph (A) as a device. Notwithstanding the preceding sentence, when assessing the safety and effectiveness of the device function or functions of such product described in subparagraph (B), the Secretary may assess the impact that the software function or functions described in subparagraph (A) have on such device function or functions.

(3)

(A) Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if—

(i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences; and

(ii) the software function has been identified in a final order issued by the Secretary under subparagraph (B).

. . . .

(4) Nothing in this subsection shall be construed as limiting the authority of the Secretary to—

(A) exercise enforcement discretion as to any device subject to regulation under this chapter;

(B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or

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(C) regulate software as a device under this chapter if such software meets the criteria under section 513(a)(1)(C).

. . . .

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FFDCA § 521. State and local requirements respecting devices [21 U.S.C. § 360k]

(a) General rule

Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this Act.

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PART E - GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES (§§ 561-567)

FFDCA § 561. Expanded access to unapproved therapies and diagnostics [21 U.S.C. § 360bbb]

(a) Emergency situations

The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) Individual patient access to investigational products intended for serious diseases

Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g), including any regulations promulgated under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

(c) Treatment investigational new drug applications and treatment investigational device exemptions

Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an "expanded access protocol"), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

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(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

(3)

(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 505(i) or investigational device exemption in effect under section 520(g); or

(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

(5) in the case of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

. . . .

(d) Termination

The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

(e) Definitions

In this section, the terms “investigational drug”, “investigational device”, “treatment investigational new drug application”, and “treatment investigational device exemption” shall have the meanings given the terms in regulations prescribed by the Secretary.

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FFDCA § 563. Classification of products [21 U.S.C. § 360bbb-2]

(a) Request

A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this chapter for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) Statement

Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will regulate the product . . . The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) Inaction of Secretary

If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary . . . .

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FFDCA § 564. Authorization for medical products for use in emergencies [21 U.S.C. § 360bbb-3]

(a) In general

(1) Emergency uses

Notwithstanding any provision of this Act and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 505, 510(k), 512, or 515 or section 351 of the Public Health Service Act or conditionally approved under section 571 (referred to in this section as an "unapproved product"); or

(B) is approved, conditionally approved under section 571, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 571, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

. . . .

(b) Declaration of emergency or threat justifying emergency authorized use

(1) In general

The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of Title 10 or Title 50, of attack with—

(i) a biological, chemical, radiological, or nuclear agent or agents; or

(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or

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(D) the identification of a material threat pursuant to section 319F-2 of the Public Health Service Act sufficient to affect national security or the health and security of United States citizens living abroad.

(2) Termination of declaration

(A) In general

A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or

(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

. . . .

(c) Criteria for issuance of authorization

The Secretary may issue an authorization under this section with respect to the emergency use of a product only if . . . the Secretary concludes—

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;

(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—

(A) the product may be effective in diagnosing, treating, or preventing—

(i) such disease or condition; or

(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;

(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and

(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(d) Scope of authorization

An authorization of a product under this section shall state—

(1) each disease or condition that the product may be used to diagnose, prevent, or treat within the scope of the authorization;

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(2) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and

(3) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including, to the extent practicable given the circumstances of the emergency, an assessment of the available scientific evidence.

(e) Conditions of authorization

. . . .

(3) Good manufacturing practice; prescription

With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the applicable circumstances described in subsection (b)(1)—

(A) requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act . . . ;

(B) requirements established under subsection (b) or (f) of section 503 or under section 504; and

(C) requirements established under section 520(e).

. . . .

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FFDCA § 564A. Emergency use of medical products [21 U.S.C. § 360bbb-3a]

(a) Definitions

In this section:

(1) Eligible product

The term "eligible product" means a product that—

(A) is approved or cleared under this subchapter, conditionally approved under section 571, or licensed under section 351 of the Public Health Service Act;

(B)

(i) is intended for use to prevent, diagnose, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents; or

(ii) is intended for use to prevent, diagnose, or treat a serious or life-threatening disease or condition caused by a product described in clause (i); and

(C) is intended for use during the circumstances under which—

(i) a determination described in subparagraph (A), (B), or (C) of section 564(b)(1) has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(ii) the identification of a material threat described in subparagraph (D) of section 564(b)(1) has been made pursuant to section 319F-2 of the Public Health Service Act.

(2) Product

The term "product" means a drug, device, or biological product.

(b) Expiration dating

(1) In general

The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if—

(A) the expiration date extension is intended to support the United States ability to protect—

(i) the public health; or

(ii) military preparedness and effectiveness; and

(B) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

. . . .

(c) Current good manufacturing practice

(1) In general

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The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements . . . .

(d) Emergency dispensing

The requirements of subsections (b) and (f) of section 503, section 504, and section 520(e) shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 564(a)(2)(A)) and shall not be deemed adulterated or misbranded under this chapter because it is dispensed without an individual prescription, if—

(1) the product is dispensed during the circumstances described in subsection (a)(1)(C); and

(2) such dispensing without an individual prescription occurs—

(A) as permitted under the law of the State in which the product is dispensed; or

(B) in accordance with an order issued by the Secretary, for the purposes and duration of the circumstances described in subsection (a)(1)(C).

. . . .

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FFDCA § 564B. Products held for emergency use [21 U.S.C. § 360bbb-3b]

It is not a violation of any section of this chapter or of the Public Health Service Act for a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, to introduce into interstate commerce a product . . . intended for emergency use, if that product—

(1) is intended to be held and not used; and

(2) is held and not used, unless and until that product—

(A) is approved, cleared, or licensed under section 505, 510(k), 512, or 515 or section 351 of the Public Health Service Act or conditionally approved under section 571;

(B) is authorized for investigational use under section 505, 512, or 520 or section 351 of the Public Health Service Act; or

(C) is authorized for use under section 564 or section 564A.

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PART F - NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES (§§ 571-573)

FFDCA § 571. Conditional approval of new animal drugs for minor use and minor species and certain new animal drugs [21 U.S.C. § 360ccc]

(a) Application requirements

(1)

(A) Except as provided in paragraph (3), any person may file with the Secretary an application for conditional approval of—

(i) a new animal drug intended for a minor use or a minor species; or

(ii) a new animal drug not intended for a minor use or minor species—

(I) that is intended to treat a serious or life-threatening disease or condition or addresses an unmet animal or human health need; and

(II) for which the Secretary determines that a demonstration of effectiveness would require a complex or particularly difficult study or studies.

(B) The Secretary shall, not later than September 30, 2019, issue guidance or regulations further clarifying the criteria specified in subparagraph (A)(ii).

(C) An application under this paragraph shall comply in all respects with the provisions of section 512 except for subsections (a)(4), (b)(2), (c)(1), (c)(2), (c)(3), (d)(1), (e), (h), and (n) of such section unless otherwise stated in this section, and any additional provisions of this section.

(D) New animal drugs for which conditional approval is sought under this section are subject to the same safety standards that would be applied to new animal drugs under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

(A) all information necessary to meet the requirements of section 512(b)(1) except section 512(b)(1)(A) ;

(B) full reports of investigations which have been made to show whether or not such drug is safe under section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and there is a reasonable expectation of effectiveness for use;

(C) data for establishing a conditional dose;

(D) projections of expected need and the justification for that expectation based on the best information available;

(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

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(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 512(d)(1)(E) within 5 years.

(3)

(A) A person may not file an application under paragraph (1) if—

(i) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal[;]

. . . .

(b) Order of approval or hearing

Within 180 days after the filing of an application pursuant to subsection (a) , or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

(1) issue an order, effective for one year, conditionally approving the application if the Secretary finds that none of the grounds for denying conditional approval, specified in subsection (c) applies and publish a Federal Register notice of the conditional approval, or

(2) give the applicant notice of an opportunity for an informal hearing on the question whether such application can be conditionally approved.

(c) Order of approval or refusal after hearing

If the Secretary finds, after giving the applicant notice and an opportunity for an informal hearing, that—

(1) any of the provisions of section 512(d)(1)(A) through (D) or (F) through (I) are applicable;

(2) the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such drug, is insufficient to show that there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

(3) another person has received approval under section 512 for the same drug in the same dosage form for the same intended use, and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended;

the Secretary shall issue an order refusing to conditionally approve the application. If, after such notice and opportunity for an informal hearing, the Secretary finds that paragraphs (1) through (3) do not apply, the Secretary shall issue an order conditionally approving the application effective for one year and publish a Federal Register notice of the conditional approval. Any order issued under this subsection refusing to conditionally approve an application shall state the findings upon which it is based.

(d) Effective period; renewal; refusal of renewal

A conditional approval under this section is effective for a 1-year period and is thereafter renewable by the Secretary annually for up to 4 additional 1-year terms. A conditional approval shall be in effect for no more than 5 years from the date of approval under subsection (b)(1) or (c) of this section unless extended as provided for in subsection (h) of this section. . . .

. . . .

(f) Labeling

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(1) The label and labeling of a new animal drug with a conditional approval under this section shall for the conditionally approved use—

(A) bear the statement, "conditionally approved by FDA pending a full demonstration of effectiveness under application number"; and

(B) contain such other information as prescribed by the Secretary.

(2) The Secretary shall, through regulation or guidance, determine under what conditions an intended use that is the subject of a conditional approval under this section may be included in the same product label with any intended use approved under section 512.

(g) Amendment of application

A conditionally approved new animal drug application may not be amended or supplemented to add indications for use.

(h) Order of approval after conditional approval period termination

180 days prior to the termination date established under subsection (d), an applicant shall have submitted all the information necessary to support a complete new animal drug application in accordance with section 512(b)(1) or the conditional approval issued under this section is no longer in effect. Following review of this information, the Secretary shall either—

(1) issue an order approving the application under section 512(c) if the Secretary finds that none of the grounds for denying approval specified in section 512(d)(1) applies, or

(2) give the applicant an opportunity for a hearing before the Secretary under sectfion 512(d) on the question whether such application can be approved.

Upon issuance of an order approving the application, product labeling and administrative records of approval shall be modified accordingly. If the Secretary has not issued an order under section 512(c) approving such application prior to the termination date established under subsection (d) , the conditional approval issued under this section is no longer in effect unless the Secretary grants an extension of an additional 180-day period so that the Secretary can complete review of the application. The decision to grant an extension is committed to the discretion of the Secretary and not subject to judicial review.

. . . .

(j) Definition

In this section and section 572 , the term "transgenic animal" means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal; Provided that the term "transgenic animal" does not include an animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

(k) Sunset

(1) The Secretary's authority to grant conditional approval of new animal drugs not intended for a minor use or minor species pursuant to subsection (a)(1)(A)(ii) terminates on October 1, 2028.

(2) The Secretary—

(A) may not accept any new applications for such conditional approval pursuant to [subsection] (a)(1)(A)(ii) on or after such date; and

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(B) may continue all activities under this section with respect to drugs that were conditionally approved pursuant to [subsection] (a)(1)(A)(ii) prior to such date.

(3) The Secretary may, until October 1, 2032, accept applications for approval under [section] 512 of drugs conditionally approved pursuant to [subsection] (a)(1)(A)(ii).

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FFDCA § 572. Index of legally marketed unapproved new animal drugs for minor species [21 U.S.C. § 360ccc-1]

(a) Establishment and content

(1) The Secretary shall establish an index limited to—

(A) new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and

(B) new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance).

(2) The index shall not include a new animal drug that is contained in or a product of a transgenic animal.

. . . .

(c) Request for determination of eligibility for inclusion in index

(1) Any person may submit a request to the Secretary for a determination whether a new animal drug may be eligible for inclusion in the index. Such a request shall include—

(A) information regarding the need for the new animal drug, the species for which the new animal drug is intended, the proposed intended use and conditions of use, and anticipated annual distribution;

(B) information to support the conclusion that the proposed use meets the conditions of subparagraph (A) or (B) of subsection (a)(1) of this section;

(C) information regarding the components and composition of the new animal drug;

(D) a description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug;

(E) an environmental assessment that meets the requirements of the National Environmental Policy Act of 1969, as amended, and as defined in 21 CFR Part 25, as it appears on August 2, 2004, and amended thereafter or information to support a categorical exclusion from the requirement to prepare an environmental assessment;

(F) information sufficient to support the conclusion that the proposed use of the new animal drug is safe under section 512(d) with respect to individuals exposed to the new animal drug through its manufacture or use; and

(G) such other information as the Secretary may deem necessary to make this eligibility determination.

(2) Within 90 days after the submission of a request for a determination of eligibility for indexing based on subsection (a)(1)(A) of this section, or 180 days for a request submitted based on subsection (a)(1)(B)

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of this section, the Secretary shall grant or deny the request, and notify the person who requested such determination of the Secretary's decision. The Secretary shall grant the request if the Secretary finds that—

(A) the same drug in the same dosage form for the same intended use is not approved or conditionally approved;

(B) the proposed use of the drug meets the conditions of subparagraph (A) or (B) of subsection (a)(1), as appropriate;

(C) the person requesting the determination has established appropriate specifications for the manufacture and control of the new animal drug and has demonstrated an understanding of the requirements of current good manufacturing practices;

(D) the new animal drug will not significantly affect the human environment; and

(E) the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use.

If the Secretary denies the request, the Secretary shall thereafter provide due notice and an opportunity for an informal conference. A decision of the Secretary to deny an eligibility request following an informal conference shall constitute final agency action subject to judicial review.

(d) Request for addition to index

(1) With respect to a new animal drug for which the Secretary has made a determination of eligibility under subsection (c), the person who made such a request may ask that the Secretary add the new animal drug to the index established under subsection (a). The request for addition to the index shall include—

(A) a copy of the Secretary's determination of eligibility issued under subsection (c);

(B) a written report that meets the requirements in subsection (d)(2) of this section;

(C) a proposed index entry;

(D) facsimile labeling;

(E) anticipated annual distribution of the new animal drug;

(F) a written commitment to manufacture the new animal drug and animal feeds bearing or containing such new animal drug according to current good manufacturing practices;

(G) a written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

(H) upon specific request of the Secretary, information submitted to the expert panel described in paragraph (3); and

(I) any additional requirements that the Secretary may prescribe by general regulation or specific order.

. . . .

(g) Regulations concerning exemptions for investigational use

For purposes of indexing new animal drugs under this section, to the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of section 512 minor species new animal drugs and animal feeds bearing or containing new animal drugs intended solely for

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investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of minor species animal drugs. . . .

(h) Labeling contents

The labeling of a new animal drug that is the subject of an index listing shall state, prominently and conspicuously—

(1) "LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF #" (followed by the applicable minor species index file number and a period) "Extra-label use is prohibited.";

(2) except in the case of new animal drugs indexed for use in an early life stage of a food-producing animal, "This product is not to be used in animals intended for use as food for humans or food-producing animals."; and

(3) such other information as may be prescribed by the Secretary in the index listing.

. . . .

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FFDCA § 573. Designated new animal drugs for minor use or minor species [21 U.S.C. § 360ccc-2]

(a) Designation

(1) The manufacturer or the sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare that drug a "designated new animal drug". A request for designation of a new animal drug shall be made before the submission of an application under section 512(b) or section 571 for the new animal drug.

(2) The Secretary may declare a new animal drug a "designated new animal drug" if—

(A) it is intended for a minor use or use in a minor species; and

(B) the same drug in the same dosage form for the same intended use is not approved under section 512 or 571 or designated under this section at the time the request is made.

. . . .

(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

(b) Grants and contracts for development of designated new animal drugs

(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

(2) For purposes of paragraph (1) of this section—

(A) The term "qualified safety and effectiveness testing" means testing—

(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 512; and

(ii) which is carried out under an investigational exemption under section 512(j).

(B) The term "manufacturing expenses" means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 512 or 571.

(c) Exclusivity for designated new animal drugs

(1) Except as provided in subsection (c)(2), if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as the designated new animal drug for another applicant before the expiration of seven years from the date of approval or conditional approval of the application.

. . . .

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CHAPTER VI—COSMETICS (§§ 601-614)

FFDCA § 601. Adulterated cosmetics [21 U.S.C. § 361]

A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual, except that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon:

> "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.",

and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a).

(f) If it has been manufactured or processed under conditions that do not meet the good manufacturing practice requirements of section 606.

(g) If it is a cosmetic product, and the cosmetic product, including each ingredient in the cosmetic product, does not have adequate substantiation for safety, as defined in section 608(c).

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FFDCA § 602. Misbranded cosmetics [21 U.S.C. § 362]

A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing

(1) the name and place of business of the manufacturer, packer, or distributor; and

(2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and

(3) the information required under section 609:

Provided, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 721. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).

(f) If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

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FFDCA § 603. Regulations making exemptions [21 U.S.C. § 363]

The Secretary shall promulgate regulations exempting from any labeling requirement of this chapter cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this chapter upon removal from such processing, labeling, or repacking establishment.

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FFDCA § 604. Definitions [21 U.S.C. § 364]

In this chapter:

(1) Adverse event

The term "adverse event" means any health-related event associated with the use of a cosmetic product that is adverse.

(2) Cosmetic product

The term "cosmetic product" means a preparation of cosmetic ingredients with a qualitatively and quantitatively set composition for use in a finished product.

(3) Facility

(A) In general

The term "facility" includes any establishment (including an establishment of an importer) that manufactures or processes cosmetic products distributed in the United States.

(B) Such term does not include any of the following:

(i) Beauty shops and salons, unless such establishment manufactures or processes cosmetic products at that location.

(ii) Cosmetic product retailers, including individual sales representatives, direct sellers . . . , retail distribution facilities, and pharmacies, unless such establishment manufactures or processes cosmetic products that are not sold directly to consumers at that location.

(iii) Hospitals, physicians' offices, and health care clinics.

(iv) Public health agencies and other nonprofit entities that provide cosmetic products directly to the consumer.

(v) Entities (such as hotels and airlines) that provide complimentary cosmetic products to customers incidental to other services.

(vi) Trade shows and other venues where cosmetic product samples are provided free of charge.

(vii) An establishment that manufactures or processes cosmetic products that are solely for use in research or evaluation, including for production testing and not offered for retail sale.

(viii) An establishment that solely performs one or more of the following with respect to cosmetic products:

(I) Labeling.

(II) Relabeling.

(III) Packaging.

(IV) Repackaging.

(V) Holding.

(VI) Distributing.

(C) Clarification

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For the purposes of subparagraph (B)(viii), the terms "packaging" and "repackaging" do not include filling a product container with a cosmetic product.

(4) Responsible person

The term "responsible person" means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609 or section 4(a) of the Fair Packaging and Labeling Act.

(5) Serious adverse event

The term "serious adverse event" means an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity;

(v) a congenital anomaly or birth defect;

(vi) an infection; or

(vii) significant disfigurement (including serious and persistent rashes, second- or third-degree burns, significant hair loss, or persistent or significant alteration of appearance), other than as intended, under conditions of use that are customary or usual; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described in subparagraph (A).

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FFDCA § 605. Adverse events [21 U.S.C. § 364a]

(a) Serious adverse event reporting requirements

The responsible person shall submit to the Secretary any report received of a serious adverse event associated with the use, in the United States, of a cosmetic product manufactured, packed, or distributed by such person.

(b) Submission of reports

. . . .

(d) Contact information

The responsible person shall receive reports of adverse events through the domestic address, domestic telephone number, or electronic contact information included on the label in accordance with section 609(a).

(e) Maintenance and inspection of adverse event records

(1) Maintenance

The responsible person shall maintain records related to each report of an adverse event associated with the use, in the United States, of a cosmetic product manufactured or distributed by such person received by such person, for a period of 6 years . . . .

(2) Inspection

(A) In general

The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

. . . .

(f) Fragrance and flavor ingredients

If the Secretary has reasonable grounds to believe that an ingredient or combination of ingredients in a fragrance or flavor has caused or contributed to a serious adverse event required to be reported under this section, the Secretary may request in writing a list of such ingredients or categories of ingredients in the specific fragrances or flavors in the cosmetic product, from the responsible person. . . .

(g) Protected information

. . . .

(h) Effect of section

. . . .

(4) Rule of construction

The submission of any report in compliance with this section shall not be construed as an admission that the cosmetic product involved caused or contributed to the relevant adverse event.

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FFDCA § 606. Good manufacturing practice [21 U.S.C. § 364b]

(a) In general

The Secretary shall by regulation establish good manufacturing practices for facilities that are consistent, to the extent practicable, and appropriate, with national and international standards, in accordance with section 601. Any such regulations shall be intended to protect the public health and ensure that cosmetic products are not adulterated. Such regulations may allow for the Secretary to inspect records necessary to demonstrate compliance with good manufacturing practices prescribed by the Secretary under this [subsection] during an inspection conducted under section 704.

(b) Considerations

In establishing regulations for good manufacturing practices under this section, the Secretary shall take into account the size and scope of the businesses engaged in the manufacture of cosmetics, and the risks to public health posed by such cosmetics, and provide sufficient flexibility to be practicable for all sizes and types of facilities to which such regulations will apply. Such regulations shall include simplified good manufacturing practice requirements for smaller businesses, as appropriate, to ensure that such regulations do not impose undue economic hardship for smaller businesses, and may include longer compliance times for smaller businesses. Before issuing regulations to implement subsection (a), the Secretary shall consult with cosmetics manufacturers, including smaller businesses, consumer organizations, and other experts selected by the Secretary.

(c) Timeframe

The Secretary shall publish a notice of proposed rulemaking not later than 2 years after [December 29, 2022], and shall publish a final such rule not later than 3 years after [December 29, 2022].

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FFDCA § 607. Registration and product listing [21 U.S.C. § 364c]

(a) Submission of registration

(1) Initial registration

(A) Existing facilities

Every person that, on [December 29, 2022], owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States shall register each facility with the Secretary not later than 1 year after [December 29, 2022].

(B) New facilities

Every person that owns or operates a facility that first engages, after [December 29, 2022], in manufacturing or processing of a cosmetic product for distribution in the United States, shall register with the Secretary such facility within 60 days of first engaging in such activity or 60 days after the deadline for registration under subparagraph (A), whichever is later.

(2) Biennial renewal of registration

A person required to register a facility under paragraph (1) shall renew such registrations with the Secretary biennially.

. . . .

(b) Format; contents of registration

(1) In general

Registration information under this section may be submitted at such time and in such manner as the Secretary may prescribe.

(2) Contents

The registration under subsection (a) shall contain—

(A) the facility's name, physical address, email address, and telephone number;

(B) with respect to any foreign facility, the contact for the United States agent of the facility, and, if available, the electronic contact information;

(C) the facility registration number, if any, previously assigned by the Secretary under subsection (d);

(D) all brand names under which cosmetic products manufactured or processed in the facility are sold; and

(E) the product category or categories and responsible person for each cosmetic product manufactured or processed at the facility.

(c) Cosmetic product listing

(1) In general

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For each cosmetic product, the responsible person shall submit to the Secretary a cosmetic product listing, or ensure that such submission is made, at such time and in such manner as the Secretary may prescribe.

(2) Cosmetic product listing

The responsible person of a cosmetic product that is marketed on [December 29, 2022], shall submit to the Secretary a cosmetic product listing not later than 1 year after [December 29, 2022], or for a cosmetic product that is first marketed after [December 29, 2022], within 120 days of marketing such product in interstate commerce. Thereafter, any updates to such listing shall be made annually, consistent with paragraphs (4) and (5).

. . . .

(4) Contents of listing

(A) In general

Each such cosmetic product listing shall include—

(i) the facility registration number of each facility where the cosmetic product is manufactured or processed;

(ii) the name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label;

(iii) the applicable cosmetic category or categories for the cosmetic product;

(iv) a list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), or by the common or usual name of the ingredient; and

(v) the product listing number, if any previously assigned by the Secretary under subsection (d).

. . . .

(d) Facility registration and product listing numbers

At the time of the initial registration of any facility under subsection (a)(1) or initial listing of any cosmetic product under (c)(1), the Secretary shall assign a facility registration number to the facility and a product listing number to each cosmetic product. The Secretary shall not make such product listing number publicly available.

(e) Confidentiality

. . . .

(f) Suspensions

(1) Suspension of registration of a facility

The Secretary may suspend the registration of a facility if the Secretary determines that a cosmetic product manufactured or processed by a registered facility and distributed in the United States has a reasonable probability of causing serious adverse health consequences or death to humans and the Secretary has a reasonable belief that other products manufactured or processed by the facility may be

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similarly affected because of a failure that cannot be isolated to a product or products, or is sufficiently pervasive to raise concerns about other products manufactured in the facility.

(2) Notice of suspension

. . . .

(3) Hearing on suspension

. . . .

(6) Effect of suspension

If the registration of the facility is suspended under this section, no person shall introduce or deliver for introduction into commerce in the United States cosmetic products from such facility.

(7) No delegation

The authority conferred by this section to issue an order to suspend a registration or vacate an order of suspension shall not be delegated to any officer or employee other than the Commissioner.

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FFDCA § 608. Safety substantiation [21 U.C.S. § 364d]

(a) Substantiation of safety

A responsible person for a cosmetic product shall ensure, and maintain records supporting, that there is adequate substantiation of safety of such cosmetic product.

(b) Coal-tar hair dye

Subsection (a) shall not apply to coal-tar hair dye that otherwise complies with the requirements of section 601(a). A responsible person for a coal-tar hair dye shall maintain records related to the safety of such product.

(c) Definitions

For purposes of this section:

(1) Adequate substantiation of safety

The term "adequate substantiation of safety" means tests or studies, research, analyses, or other evidence or information that is considered, among experts qualified by scientific training and experience to evaluate the safety of cosmetic products and their ingredients, sufficient to support a reasonable certainty that a cosmetic product is safe.

(2) Safe

The term "safe" means that the cosmetic product, including any ingredient thereof, is not injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual. The Secretary shall not consider a cosmetic ingredient or cosmetic product injurious to users solely because it can cause minor and transient reactions or minor and transient skin irritations in some users. In determining for purposes of this section whether a cosmetic product is safe, the Secretary may consider, as appropriate and available, the cumulative or other relevant exposure to the cosmetic product, including any ingredient thereof.

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FFDCA § 609. Labeling [21 U.S.C. § 364e]

*[**(a) General requirement***

Each cosmetic product shall bear a label that includes a domestic address, domestic phone number, or electronic contact information, which may include a website, through which the responsible person can receive adverse event reports with respect to such cosmetic product.][*]

(b) Fragrance allergens

The responsible person shall identify on the label of a cosmetic product each fragrance allergen included in such cosmetic product. Substances that are fragrance allergens for purposes of this subsection shall be determined by the Secretary by regulation. The Secretary shall issue a notice of proposed rulemaking promulgating the regulation implementing this requirement not later than 18 months after [December 29, 2022], and not later than 180 days after the date on which the public comment period on the proposed rulemaking closes, shall issue a final rulemaking. . . .

(c) Cosmetic products for professional use

(1) Definition of professional

For purposes of this subsection, the term "professional" means an individual who is licensed by an official State authority to practice in the field of cosmetology, nail care, barbering, or esthetics.

(2) Professional use labeling

A cosmetic product introduced into interstate commerce and intended to be used only by a professional shall bear a label that—

(A) contains a clear and prominent statement that the product shall be administered or used only by licensed professionals; and

(B) is in conformity with the requirements of the Secretary for cosmetics labeling under this Act and section 4(a) of the Fair Packaging and Labeling Act.

[*] FFDCA § 609(a), *[bracketed in gray italics]*, is scheduled to take effect "on the date that is 2 years after" the Dec. 29, 2022, enactment of the Modernization of Cosmetics Regulation Act. *See* Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 3503(b)(2).

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FFDCA § 610. Records [21 U.S.C. § 364f]

(a) In general

If the Secretary has a reasonable belief that a cosmetic product, including an ingredient in such cosmetic product, and any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, is likely to be adulterated such that the use or exposure to such product presents a threat of serious adverse health consequences or death to humans, each responsible person and facility shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such cosmetic product, and to any other cosmetic product that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether the cosmetic product is adulterated and presents a threat of serious adverse health consequences or death to humans. This subsection shall not be construed to extend to recipes or formulas for cosmetics, financial data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), research data (other than safety substantiation data for cosmetic products and their ingredients), or sales data (other than shipment data regarding sales).

(b) Rule of construction

Nothing in this section shall be construed to limit the authority of the Secretary to inspect records or require establishment and maintenance of records under any other provision of this Act, including section 605 or section 606.

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FFDCA § 611. Mandatory recall authority [21 U.S.C. § 364g]

(a) In general

If the Secretary determines that there is a reasonable probability that a cosmetic is adulterated under section 601 or misbranded under section 602 and the use of or exposure to such cosmetic will cause serious adverse health consequences or death, the Secretary shall provide the responsible person with an opportunity to voluntarily cease distribution and recall such article. If the responsible person refuses to or does not voluntarily cease distribution or recall such cosmetic within the time and manner prescribed by the Secretary (if so prescribed), the Secretary may, by order, require, as the Secretary determines necessary, such person to immediately cease distribution of such article.

(b) Hearing

The Secretary shall provide the responsible person who is subject to an order under subsection (a) with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify the order.

(c) Order resolution

After an order is issued according to the process under subsections (a) and (b), the Secretary shall, except as provided in subsection (d)—

(1) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(2) continue the order ceasing distribution of the cosmetic until a date specified in such order; or

(3) amend the order to require a recall of the cosmetic, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

(d) Action following order

Any person who is subject to an order pursuant to paragraph (2) or (3) of subsection (c) shall immediately cease distribution of or recall, as applicable, the cosmetic and provide notification as required by such order.

. . . .

(f) Public notification

. . . .

(g) No delegation

The authority conferred by this section to order a recall or vacate a recall order shall not be delegated to any officer or employee other than the Commissioner.

. . . .

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FFDCA § 612. Small businesses [21 U.S.C. § 364h]

(a) In general

Responsible persons, and owners and operators of facilities, whose average gross annual sales in the United States of cosmetic products for the previous 3-year period is less than $1,000,000 . . . and who do not engage in the manufacturing or processing of the cosmetic products described in subsection (b), shall be considered small businesses and not subject to the requirements of section 606 or section 607.

(b) Requirements applicable to all manufacturers and processors of cosmetics

The exemptions under subsection (a) shall not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products:

(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.

(2) Cosmetic products that are injected.

(3) Cosmetic products that are intended for internal use.

(4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

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FFDCA § 613. Exemption for certain products and facilities [21 U.S.C. § 364i]

(a) In general

Notwithstanding any other provision of law, except as provided in subsection (b), a cosmetic product or facility that is also subject to the requirements of chapter V shall be exempt from the requirements of sections 605, 606, 607, 608, 609(a), 610, and 611.

(b) Exception

A facility described in subsection (a) that also manufactures or processes cosmetic products that are not subject to the requirements of chapter V shall not be exempt from the requirements of sections 605, 606, 607, 608, 609(a), 610, and 611, with respect to such cosmetic products.

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FFDCA § 614. Preemption [21 U.S.C. § 364j]

(a) In general

No State or political subdivision of a State may establish or continue in effect any law, regulation, order, or other requirement for cosmetics that is different from or in addition to, or otherwise not identical with, any requirement applicable under this subchapter with respect to registration and product listing, good manufacturing practice, records, recalls, adverse event reporting, or safety substantiation.

(b) Limitation

Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022 shall be construed to preempt any State statute, public initiative, referendum, regulation, or other State action, except as expressly provided in subsection (a). Notwithstanding subsection (a), nothing in this section shall be construed to prevent any State from prohibiting the use or limiting the amount of an ingredient in a cosmetic product, or from continuing in effect a requirement of any State that is in effect at the time of enactment of the Modernization of Cosmetics Regulation Act of 2022 for the reporting to the State of an ingredient in a cosmetic product.

(c) Savings

Nothing in the amendments to this Act made by the Modernization of Cosmetics Regulation Act of 2022, nor any standard, rule, requirement, regulation, or adverse event report shall be construed to modify, preempt, or displace any action for damages or the liability of any person under the law of any State, whether statutory or based in common law.

(d) Rule of construction

Nothing in this section shall be construed to amend, expand, or limit the provisions under section 752.

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CHAPTER VII—GENERAL AUTHORITY (§§ 701-772)

PART A – GENERAL ADMINISTRATIVE PROVISIONS (§§ 701-703)

FFDCA § 701. Regulations and hearings [21 U.S.C. § 371]

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

. . . .

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act, and any action for the amendment or repeal of any definition and standard of identity under section 401 of this Act for any dairy product . . . shall be begun by a proposal made

(A) by the Secretary on his own initiative, or

(B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary.

The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. . . .

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. . . .

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by

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representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. . . .

(f) Review of order

(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. . . .

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28.

. . . .

(h) Guidance documents

(1)

(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

(C)

(i) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

(ii) With respect to devices, if a notice to industry guidance letter, a notice to industry advisory letter, or any similar notice sets forth initial interpretations of a regulation or policy or sets forth

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changes in interpretation or policy, such notice shall be treated as a guidance document for purposes of this subparagraph.

(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

(5) . . . . [T]he Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed.Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.

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FFDCA § 702. Examinations and investigations [21 U.S.C. § 372]

(a) Authority to conduct

(1)

(A) The Secretary is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

(B)

(i) For a tobacco product, to the extent feasible, the Secretary shall contract with the States in accordance with this paragraph to carry out inspections of retailers within that State in connection with the enforcement of this chapter.

(ii) The Secretary shall not enter into any contract under clause (i) with the government of any of the several States to exercise enforcement authority under this chapter on Indian country without the express written consent of the Indian tribe involved.

. . . .

(e) Powers of enforcement personnel

Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to counterfeit drugs may, when so authorized by the Secretary—

(1) carry firearms;

(2) execute and serve search warrants and arrest warrants;

(3) execute seizure by process issued pursuant to libel under section 304;

(4) make arrests without warrant for offenses under this chapter with respect to such drugs if the offense is committed in his presence or, in the case of a felony, if he has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(5) make, prior to the institution of libel proceedings under section 304(a)(2), seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 304(a)(2). In the event of seizure pursuant to this paragraph (5), libel proceedings under section 304(a)(2) shall be instituted promptly and the property seized be placed under the jurisdiction of the court.

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FFDCA § 703. Records [21 U.S.C. § 373]

(a) In general

For the purpose of enforcing the provisions of this chapter, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, tobacco products, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, tobacco product, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof . . . .

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FFDCA § 704. Inspection [21 U.S.C. § 374]

(a) Right of agents to enter; scope of inspection; notice; promptness; exclusions

(1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized

(A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and

(B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d).

In the case of a facility (as defined in section 604) that manufactures or processes cosmetic products, the inspection shall extend to all records and other information described in sections 605, 606, and 610, when the standard for records inspection under such section applies. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, devices, or tobacco products are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, devices, or tobacco products which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter. . . .

(2) The provisions of the third sentence of paragraph (1) shall not apply to—

(A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail;

(B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices, solely for use in the course of their professional practice;

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(C) persons who manufacture, prepare, propagate, compound, or process drugs or manufacture or process devices, solely for use in research, teaching, or chemical analysis and not for sale;

(D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

. . . .

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FFDCA § 705. Publicity [21 U.S.C. § 375]

(a) Reports

The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

(b) Information regarding certain goods

The Secretary may also cause to be disseminated information regarding food, drugs, devices, tobacco products, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. . . .

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FFDCA § 709. Presumption of existence of jurisdiction [21 U.S.C. § 379a]

In any action to enforce the requirements of this chapter respecting a device, tobacco product, food, drug, or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.

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PART B – COLORS (§§ 721)

FFDCA § 721. Listing and certification of color additives for foods, drugs, devices, and cosmetics [21 U.S.C. § 379e]

(a) Unsafe color additives

A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or devices or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—

(1)

(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and

(B) such additive either

(i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or

(ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)). A color additive for use in or on a device shall be subject to this section only if the color additive comes in direct contact with the body of man or other animals for a significant period of time. The Secretary may by regulation designate the uses of color additives in or on devices which are subject to this section.

(b) Listing of colors; regulations; issuance, amendment or repeal; referral to advisory committee; report and recommendations; appointment and compensation of advisory committee

(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, or devices, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2)

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(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs or devices, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: Provided, however, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(5)

(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of

(I) the pure dye and all intermediates and other impurities contained in such color additive,

(II) such additive in or on any article of food, drug or device, or cosmetic, and

(III) any substance formed in or on such article because of the use of such additive.

(B) A color additive

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(i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and

(ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal:

Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

(C)

(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. . . .

(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. . . . Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

. . . .

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. . . .

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(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety),

(A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses;

(B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and

(C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

(c) Certification of colors

The Secretary shall further, by regulation, provide

(1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and

(2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health:

Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(d) Procedure for issuance, amendment, or repeal of regulations

The provisions of section 701(e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section, apply to and in all respects govern proceedings for the issuance,

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amendment, or repeal of regulations under subsection (b) or (c) (including judicial review of the Secretary's action in such proceedings) . . . .

(e) Fees

The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

(f) Exemptions

The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or device, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

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CHAPTER VIII—IMPORTS AND EXPORTS (§§ 801-809)

FFDCA § 801. Imports and exports [21 U.S.C. § 381]

(a) Imports; list of registered foreign establishments; samples from unregistered foreign establishments; examination and refusal of admission

The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, tobacco products, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 or section 905(h) and shall request that if any drugs, devices, or tobacco products manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs, devices, or tobacco products be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that

(1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or

(2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or

(3) such article is adulterated, misbranded, or in violation of section 505 or the importer (as defined in section 805) is in violation of such section 805, or prohibited from introduction or delivery for introduction into interstate commerce under section 301(ll), or is a controlled substance subject to an order under section 569D, or

(4) the recordkeeping requirements under section 204 of the FDA Food Safety Modernization Act (other than the requirements under subsection (f) of such section) have not been complied with regarding such article[,] or

(5) such article is being imported or offered for import in violation of section 301(cc), then any such article described in any of clauses (1) through (5) shall be refused admission, except as provided in subsection (b) of this section.

If it appears from the examination of such samples or otherwise that the article is a counterfeit drug or counterfeit device, such article shall be refused admission. With respect to an article of food, if importation of such food is subject to, but not compliant with, the requirement under subsection (q) that such food be accompanied by a certification or other assurance that the food meets applicable requirements of this chapter, then such article shall be refused admission. If such article is subject to a requirement under section 605, 760, or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 604, 760, or 761) has not complied with a requirement of such section

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605, 760, or 761 with respect to any such article, or has not allowed access to records described in such section 605, 760, or 761, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations . . . .

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FFDCA § 803. Office of International Relations [21 U.S.C. § 383]

(a) Establishment

There is established in the Department of Health and Human Services an Office of International Relations.

(b) Agreements with foreign countries

In carrying out the functions of the office under subsection (a), the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 520(f), and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(c) Harmonizing regulatory requirements

(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this chapter.

(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

(3)

(A) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

. . . .

(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 201(ff).

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FFDCA § 804. Importation of prescription drugs [21 U.S.C. § 384]

(a) Definitions

In this section:

(1) Importer

The term "importer" means a pharmacist or wholesaler.

(2) Pharmacist

The term "pharmacist" means a person licensed by a State to practice pharmacy, including the dispensing and selling of prescription drugs.

(3) Prescription drug

The term "prescription drug" means a drug subject to section 503(b), other than—

(A) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

(B) a biological product (as defined in section 351 of the Public Health Services Act (42 U.S.C. 262))

(C) an infused drug (including a peritoneal dialysis solution);

(D) an intravenously injected drug;

(E) a drug that is inhaled during surgery; or

(F) a drug which is a parenteral drug, the importation of which pursuant to subsection (b) is determined by the Secretary to pose a threat to the public health, in which case section 801(d)(1) shall continue to apply.

(4) Qualifying laboratory

The term "qualifying laboratory" means a laboratory in the United States that has been approved by the Secretary for the purposes of this section.

(5) Wholesaler

(A) In general

The term "wholesaler" means a person licensed as a wholesaler or distributor of prescription drugs in the United States under section 503(e)(2)(A).

(B) Exclusion

The term "wholesaler" does not include a person authorized to import drugs under section 801(d)(1).

(b) Regulations

The Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, shall promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.

(c) Limitation

The regulations under subsection (b) shall—

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(1) require that safeguards be in place to ensure that each prescription drug imported under the regulations complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of this chapter;

(2) require that an importer of a prescription drug under the regulations comply with subsections (d)(1) and (e); and

(3) contain any additional provisions determined by the Secretary to be appropriate as a safeguard to protect the public health or as a means to facilitate the importation of prescription drugs.

. . . .

(f) Registration of foreign sellers

Any establishment within Canada engaged in the distribution of a prescription drug that is imported or offered for importation into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

. . . .

(j) Waiver authority for importation by individuals

(1) Declarations

Congress declares that in the enforcement against individuals of the prohibition of importation of prescription drugs and devices, the Secretary should—

(A) focus enforcement on cases in which the importation by an individual poses a significant threat to public health; and

(B) exercise discretion to permit individuals to make such importations in circumstances in which—

(i) the importation is clearly for personal use; and

(ii) the prescription drug or device imported does not appear to present an unreasonable risk to the individual.

(2) Waiver authority

(A) In general

The Secretary may grant to individuals, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug or device or class of prescription drugs or devices, under such conditions as the Secretary determines to be appropriate.

(B) Guidance on case-by-case waivers

The Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

(3) Drugs imported from Canada

In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—

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(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply;

(B) is accompanied by a copy of a valid prescription;

(C) is imported from Canada, from a seller registered with the Secretary;

(D) is a prescription drug approved by the Secretary under subchapter V;

(E) is in the form of a final finished dosage that was manufactured in an establishment registered under section 510; and

(F) is imported under such other conditions as the Secretary determines to be necessary to ensure public safety.

. . . .

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FFDCA § 805. Foreign supplier verification program [21 U.S.C. § 384a]

(a) In general

(1) Verification requirement

Except as provided under subsections (e) and (f), each importer shall perform risk-based foreign supplier verification activities for the purpose of verifying that the food imported by the importer or agent of an importer is—

(A) produced in compliance with the requirements of section 418 or section 419, as appropriate; and

(B) is not adulterated under section 402 or misbranded under section 403(w).

(2) Importer defined

For purposes of this section, the term "importer" means, with respect to an article of food—

(A) the United States owner or consignee of the article of food at the time of entry of such article into the United States; or

(B) in the case when there is no United States owner or consignee as described in subparagraph (A), the United States agent or representative of a foreign owner or consignee of the article of food at the time of entry of such article into the United States.

. . . .

(c) Regulations

(1) In general

. . . the Secretary shall promulgate regulations to provide for the content of the foreign supplier verification program established under subsection (a).

(2) Requirements

The regulations promulgated under paragraph (1)—

(A) shall require that the foreign supplier verification program of each importer be adequate to provide assurances that each foreign supplier to the importer produces the imported food in compliance with—

(i) processes and procedures, including reasonably appropriate risk-based preventive controls, that provide the same level of public health protection as those required under section 418 or section 419 (taking into consideration variances granted under section 419), as appropriate; and

(ii) section 402 and section 403(w)[; and]

(B) shall include such other requirements as the Secretary deems necessary and appropriate to verify that food imported into the United States is as safe as food produced and sold within the United States.

(3) Considerations

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In promulgating regulations under this subsection, the Secretary shall, as appropriate, take into account differences among importers and types of imported foods, including based on the level of risk posed by the imported food.

(4) Activities

Verification activities under a foreign supplier verification program under this section may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of the foreign supplier, and periodically testing and sampling shipments.

. . . .

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FFDCA § 806. Voluntary qualified importer program [21 U.S.C. § 384b]

(a) In general

. . . the Secretary shall—

(1) establish a program, in consultation with the Secretary of Homeland Security—

(A) to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program; and

(B) consistent with section 808, establish a process for the issuance of a facility certification to accompany food offered for importation by importers who have voluntarily agreed to participate in such program; and

(2) issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with, such program.

(b) Voluntary participation

An importer may request the Secretary to provide for the expedited review and importation of designated foods in accordance with the program established by the Secretary under subsection (a).

. . . .

(d) Eligibility

Eligibility shall be limited to an importer offering food for importation from a facility that has a certification described in subsection (a). . . .

. . . .

(g) Definition

For purposes of this section, the term "importer" means the person that brings food, or causes food to be brought, from a foreign country into the customs territory of the United States.

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FFDCA § 807. Inspection of foreign food facilities [21 U.S.C. § 384c]

(a) Inspection

The Secretary—

(1) may enter into arrangements and agreements with foreign governments to facilitate the inspection of foreign facilities registered under section 415; and

(2) shall direct resources to inspections of foreign facilities, suppliers, and food types, especially such facilities, suppliers, and food types that present a high risk (as identified by the Secretary), to help ensure the safety and security of the food supply of the United States.

(b) Effect of inability to inspect

Notwithstanding any other provision of law, food shall be refused admission into the United States if it is from a foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment. For purposes of this subsection, such an owner, operator, or agent in charge shall be considered to have refused an inspection if such owner, operator, or agent in charge does not permit an inspection of a factory, warehouse, or other establishment during the 24-hour period after such request is submitted, or after such other time period, as agreed upon by the Secretary and the foreign factory, warehouse, or other establishment.

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FFDCA § 808. Accreditation of third-party auditors [21 U.S.C. § 384d]

(a) Definitions

In this section:

(1) Audit agent

The term "audit agent" means an individual who is an employee or agent of an accredited third-party auditor and, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party auditor.

(2) Accreditation body

The term "accreditation body" means an authority that performs accreditation of third-party auditors.

(3) Third-party auditor

The term "third-party auditor" means a foreign government, agency of a foreign government, foreign cooperative, or any other third party, as the Secretary determines appropriate in accordance with the model standards described in subsection (b)(2), that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements of this section. A third-party auditor may be a single individual. A third-party auditor may employ or use audit agents to help conduct consultative and regulatory audits.

(4) Accredited third-party auditor

The term "accredited third-party auditor" means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section. An accredited third-party auditor may be an individual who conducts food safety audits to certify that eligible entities meet the applicable requirements of this section.

(5) Consultative audit

The term "consultative audit" means an audit of an eligible entity—

(A) to determine whether such entity is in compliance with the provisions of this chapter and with applicable industry standards and practices; and

(B) the results of which are for internal purposes only.

(6) Eligible entity

The term "eligible entity" means a foreign entity, including a foreign facility registered under section 415, in the food import supply chain that chooses to be audited by an accredited third-party auditor or the audit agent of such accredited third-party auditor.

(7) Regulatory audit

The term "regulatory audit" means an audit of an eligible entity—

(A) to determine whether such entity is in compliance with the provisions of this chapter; and

(B) the results of which determine—

(i) whether an article of food manufactured, processed, packed, or held by such entity is eligible to receive a food certification under section 801(q); or

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(ii) whether a facility is eligible to receive a facility certification under section 806(a) for purposes of participating in the program under section 806

. . . .

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FFDCA § 809. Recognition of foreign government inspections [21 U.S.C. § 384e]

(a) Inspection

The Secretary—

(1) may enter into arrangements and agreements with a foreign government or an agency of a foreign government to recognize the inspection of foreign establishments registered under section 510(i) in order to facilitate preapproval or risk-based inspections in accordance with the schedule established in paragraph (2) or (3) of section 510(h);

(2) may enter into arrangements and agreements with a foreign government or an agency of a foreign government under this section only with a foreign government or an agency of a foreign government that the Secretary has determined as having the capability of conducting inspections that meet the applicable requirements of this chapter; and

(3) shall perform such reviews and audits of drug safety programs, systems, and standards of a foreign government or agency for the foreign government as the Secretary deems necessary to determine that the foreign government or agency of the foreign government is capable of conducting inspections that meet the applicable requirements of this chapter.

(b) Results of inspection

The results of inspections performed by a foreign government or an agency of a foreign government under this section may be used as—

(1) evidence of compliance with section 501(a)(2)(B) or section 801(r); and

(2) for any other purposes as determined appropriate by the Secretary.

(c) Periodic review

. . . .

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CHAPTER IX—TOBACCO PRODUCTS (§§ 900-920)

FFDCA § 900. Definitions [21 U.S.C. § 387]

In this subchapter:

(1) Additive

The term "additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical.

(2) Brand

The term "brand" means a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, identifiable pattern of colors, or any combination of such attributes.

(3) Cigarette

The term "cigarette"—

(A) means a product that—

(i) is a tobacco product; and

(ii) meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(B) includes tobacco, in any form, that is functional in the product, which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette or as roll-your-own tobacco.

(4) Cigarette tobacco

The term "cigarette tobacco" means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this subchapter shall also apply to cigarette tobacco.

. . . .

(6) Counterfeit tobacco product

The term "counterfeit tobacco product" means a tobacco product (or the container or labeling of such a product) that, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a tobacco product listed in a registration under section 905(i)(1).

(7) Distributor

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The term "distributor" as regards a tobacco product means any person who furthers the distribution of a tobacco product, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for purposes of this subchapter.

(8) Illicit trade

The term "illicit trade" means any practice or conduct prohibited by law which relates to production, shipment, receipt, possession, distribution, sale, or purchase of tobacco products including any practice or conduct intended to facilitate such activity.

. . . .

(11) Little cigar

The term "little cigar" means a product that—

(A) is a tobacco product; and

(B) meets the definition of the term "little cigar" in section 3(7) of the Federal Cigarette Labeling and Advertising Act.

(12) Nicotine

The term "nicotine" means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl) pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

(13) Package

The term "package" means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including cellophane), in which a tobacco product is offered for sale, sold, or otherwise distributed to consumers.

(14) Retailer

The term "retailer" means any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted.

(15) Roll-your-own tobacco

The term "roll-your-own tobacco" means any tobacco product which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers as tobacco for making cigarettes.

. . . .

(17) Smoke constituent

The term "smoke constituent" means any chemical or chemical compound in mainstream or sidestream tobacco smoke that either transfers from any component of the cigarette to the smoke or that is formed by the combustion or heating of tobacco, additives, or other component of the tobacco product.

(18) Smokeless tobacco

The term "smokeless tobacco" means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

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(20) Tobacco product manufacturer

The term "tobacco product manufacturer" means any person, including any repacker or relabeler, who—

(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or

(B) imports a finished tobacco product for sale or distribution in the United States.

(21) Tobacco warehouse

(A) Subject to subparagraphs (B) and (C), the term "tobacco warehouse" includes any person—

(i) who—

(I) removes foreign material from tobacco leaf through nothing other than a mechanical process;

(II) humidifies tobacco leaf with nothing other than potable water in the form of steam or mist; or

(III) de-stems, dries, and packs tobacco leaf for storage and shipment;

(ii) who performs no other actions with respect to tobacco leaf; and

(iii) who provides to any manufacturer to whom the person sells tobacco all information related to the person's actions described in clause (i) that is necessary for compliance with this Act.

(B) The term "tobacco warehouse" excludes any person who—

(i) reconstitutes tobacco leaf;

(ii) is a manufacturer, distributor, or retailer of a tobacco product; or

(iii) applies any chemical, additive, or substance to the tobacco leaf other than potable water in the form of steam or mist.

(C) The definition of the term "tobacco warehouse" in subparagraph (A) shall not apply to the extent to which the Secretary determines, through rulemaking, that regulation under this subchapter of the actions described in such subparagraph is appropriate for the protection of the public health.

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FFDCA § 901. FDA authority over tobacco products [21 U.S.C. § 387a]

(a) In general

Tobacco products, including modified risk tobacco products for which an order has been issued in accordance with section 911, shall be regulated by the Secretary under this chapter and shall not be subject to the provisions of chapter V.

(b) Applicability

This chapter shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this chapter. This chapter shall also apply to any tobacco product containing nicotine that is not made or derived from tobacco.

(c) Scope

(1) In general

Nothing in this chapter, or any policy issued or regulation promulgated thereunder, or in sections 101(a), 102, or 103 of Title I, Title II, or Title III of the Family Smoking Prevention and Tobacco Control Act, shall be construed to affect, expand, or limit the Secretary's authority over (including the authority to determine whether products may be regulated), or the regulation of, products under this chapter that are not tobacco products under chapter V or any other chapter.

(2) Limitation of authority

(A) In general

The provisions of this chapter shall not apply to tobacco leaf that is not in the possession of a manufacturer of tobacco products, or to the producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, nor shall any employee of the Food and Drug Administration have any authority to enter onto a farm owned by a producer of tobacco leaf without the written consent of such producer.

(B) Exception

Notwithstanding subparagraph (A), if a producer of tobacco leaf is also a tobacco product manufacturer or controlled by a tobacco product manufacturer, the producer shall be subject to this chapter in the producer's capacity as a manufacturer. The exception in this subparagraph shall not apply to a producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process.

(C) Rule of construction

Nothing in this chapter shall be construed to grant the Secretary authority to promulgate regulations on any matter that involves the production of tobacco leaf or a producer thereof, other than activities by a manufacturer affecting production.

(d) Rulemaking procedures

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Each rulemaking under this chapter shall be in accordance with chapter 5 of Title 5. This subsection shall not be construed to affect the rulemaking provisions of section 102(a) of the Family Smoking Prevention and Tobacco Control Act.

(e) Center for Tobacco Products

Not later than 90 days after June 22, 2009, the Secretary shall establish within the Food and Drug Administration the Center for Tobacco Products, which shall report to the Commissioner of Food and Drugs in the same manner as the other agency centers within the Food and Drug Administration. The Center shall be responsible for the implementation of this chapter and related matters assigned by the Commissioner.

(f) Office to assist small tobacco product manufacturers

The Secretary shall establish within the Food and Drug Administration an identifiable office to provide technical and other nonfinancial assistance to small tobacco product manufacturers to assist them in complying with the requirements of this chapter.

(g) Consultation prior to rulemaking

Prior to promulgating rules under this chapter, the Secretary shall endeavor to consult with other Federal agencies as appropriate.

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FFDCA § 902. Adulterated tobacco products [21 U.S.C. § 387b]

A tobacco product shall be deemed to be adulterated if—

(1) it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise contaminated by any added poisonous or added deleterious substance that may render the product injurious to health;

(2) it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health;

(3) its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(4) the manufacturer or importer of the tobacco product fails to pay a user fee assessed to such manufacturer or importer pursuant to section 919 by the date specified in section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of such fee;

(5) it is, or purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907 unless such tobacco product is in all respects in conformity with such standard;

(6)

(A) it is required by section 910(a) to have premarket review and does not have an order in effect under section 910(c)(1)(A)(i); or

(B) it is in violation of an order under section 910(c)(1)(A);

(7) the methods used in, or the facilities or controls used for, its manufacture, packing, or storage are not in conformity with applicable requirements under section 906(e)(1) or an applicable condition prescribed by an order under section 906(e)(2); or

(8) it is in violation of section 911.

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FFDCA § 903. Misbranded tobacco products [21 U.S.C. § 387c]

(a) In general

A tobacco product shall be deemed to be misbranded—

(1) if its labeling is false or misleading in any particular;

(2) if in package form unless it bears a label containing—

(A) the name and place of business of the tobacco product manufacturer, packer, or distributor;

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

(C) an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage that is foreign grown tobacco; and

(D) the statement required under section 920(a),

except that under subparagraph (B) reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary;

(3) if any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, or designs in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(4) if it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name prominently printed in type as required by the Secretary by regulation;

(5) if the Secretary has issued regulations requiring that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users unless its labeling conforms in all respects to such regulations;

(6) if it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905(b), 905(c), 905(d), or 905(h), if it was not included in a list required by section 905(i), if a notice or other information respecting it was not provided as required by such section or section 905(j), or if it does not bear such symbols from the uniform system for identification of tobacco products prescribed under section 905(e) as the Secretary by regulation requires;

(7) if, in the case of any tobacco product distributed or offered for sale in any State—

(A) its advertising is false or misleading in any particular; or

(B) it is sold or distributed in violation of section 906(d)(5) or of regulations prescribed under section 906(d);

(8) unless, in the case of any tobacco product distributed or offered for sale in any State, the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that tobacco product—

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(A) a true statement of the tobacco product's established name as described in paragraph (4), printed prominently; and

(B) a brief statement of—

(i) the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications; and

(ii) in the case of specific tobacco products made subject to a finding by the Secretary after notice and opportunity for comment that such action is appropriate to protect the public health, a full description of the components of such tobacco product or the formula showing quantitatively each ingredient of such tobacco product to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing;

(9) if it is a tobacco product subject to a tobacco product standard established under section 907, unless it bears such labeling as may be prescribed in such tobacco product standard; or

(10) if there was a failure or refusal—

(A) to comply with any requirement prescribed under section 904 or 908; or

(B) to furnish any material or information required under section 909.

(b) Prior approval of label statements

The Secretary may, by regulation, require prior approval of statements made on the label of a tobacco product to ensure that such statements do not violate the misbranding provisions of subsection (a) and that such statements comply with other provisions of the Family Smoking Prevention and Tobacco Control Act (including the amendments made by such Act). No regulation issued under this subsection may require prior approval by the Secretary of the content of any advertisement, except for modified risk tobacco products as provided in section 911. . . .

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FFDCA § 905. Annual registration [21 U.S.C. § 387e]

(a) Definitions

In this section:

(1) Manufacture, preparation, compounding, or processing

The term "manufacture, preparation, compounding, or processing" shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

(2) Name

The term "name" shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

(b) Registration by owners and operators

On or before December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products shall register with the Secretary the name, places of business, and all such establishments of that person. If enactment of the Family Smoking Prevention and Tobacco Control Act occurs in the second half of the calendar year, the Secretary shall designate a date no later than 6 months into the subsequent calendar year by which registration pursuant to this subsection shall occur.

(c) Registration by new owners and operators

Every person upon first engaging in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products in any establishment owned or operated in any State by that person shall immediately register with the Secretary that person's name, place of business, and such establishment.

(d) Registration of added establishments

Every person required to register under subsection (b) or (c) shall immediately register with the Secretary any additional establishment which that person owns or operates in any State and in which that person begins the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products.

(e) Uniform product identification system

The Secretary may by regulation prescribe a uniform system for the identification of tobacco products and may require that persons who are required to list such tobacco products under subsection (i) shall list such tobacco products in accordance with such system.

(f) Public access to registration information

The Secretary shall make available for inspection, to any person so requesting, any registration filed under this section.

(g) Biennial inspection of registered establishments

Every establishment registered with the Secretary under this section shall be subject to inspection under section 704 or subsection (h), and every such establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products shall be so inspected by 1 or more officers or employees

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duly designated by the Secretary at least once in the 2-year period beginning with the date of registration of such establishment under this section and at least once in every successive 2-year period thereafter.

(h) Registration by foreign establishments

Any establishment within any foreign country engaged in the manufacture, preparation, compounding, or processing of a tobacco product or tobacco products, shall register under this section under regulations promulgated by the Secretary. Such regulations shall require such establishment to provide the information required by subsection (i) and shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether tobacco products manufactured, prepared, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).

(i) Registration information

(1) Product list

Every person who registers with the Secretary under subsection (b), (c), (d), or (h) shall, at the time of registration under any such subsection, file with the Secretary a list of all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution and which have not been included in any list of tobacco products filed by that person with the Secretary under this paragraph or paragraph (2) before such time of registration. . . .

(3) Biannual report of any change in product list

Each person who registers with the Secretary under this section shall report to the Secretary once during the month of June of each year and once during the month of December of each year the following:

(A) A list of each tobacco product introduced by the registrant for commercial distribution which has not been included in any list previously filed by that person . . . .

(B) If since the date the registrant last made a report under this paragraph that person has discontinued the manufacture, preparation, compounding, or processing for commercial distribution of a tobacco product included in a list filed under subparagraph (A) or paragraph (1), notice of such discontinuance . . . .

(C) If since the date the registrant reported under subparagraph (B) a notice of discontinuance that person has resumed the manufacture, preparation, compounding, or processing for commercial distribution of the tobacco product with respect to which such notice of discontinuance was reported, notice of such resumption . . . .

(D) Any material change in any information previously submitted under this paragraph or paragraph (1).

(j) Report preceding introduction of certain substantially equivalent products into interstate commerce

(1) In general

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the

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United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

(A) the basis for such person's determination that—

(i) the tobacco product is substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that is in compliance with the requirements of this chapter; or

(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this chapter, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

(B) action taken by such person to comply with the requirements under section 907 that are applicable to the tobacco product.

(2) Application to certain post-February 15, 2007, products

A report under this subsection for a tobacco product that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009, shall be submitted to the Secretary not later than 21 months after June 22, 2009.

(3) Exemptions

(A) In general

The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

(i) such modification would be a minor modification of a tobacco product that can be sold under this chapter;

(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(iii) an exemption is otherwise appropriate.

(B) Regulations

Not later than 15 months after June 22, 2009, the Secretary shall issue regulations to implement this paragraph.

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FFDCA § 906. General provisions respecting control of tobacco products [21 U.S.C. § 387f]

. . . .

(d) Restrictions

(1) In general

The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health. The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

No such regulation may require that the sale or distribution of a tobacco product be limited to the written or oral authorization of a practitioner licensed by law to prescribe medical products.

(2) Label statements

The label of a tobacco product shall bear such appropriate statements of the restrictions required by a regulation under subsection (a) as the Secretary may in such regulation prescribe.

(3) Limitations

(A) In general

No restrictions under paragraph (1) may—

(i) prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets; or

(ii) establish a minimum age of sale of tobacco products to any person older than 21 years of age.

. . . .

(5) Minimum Age of Sale

It shall be unlawful for any retailer to sell a tobacco product to any person younger than 21 years of age.

(e) Good manufacturing practice requirements

(1) Methods, facilities, and controls to conform

(A) In general

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In applying manufacturing restrictions to tobacco, the Secretary shall, in accordance with subparagraph (B), prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this chapter. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

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(2) Exemptions; Variances

(A) Petition

Any person subject to any requirement prescribed under paragraph (1) may petition the Secretary for a permanent or temporary exemption or variance from such requirement. . . .

. . . .

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FFDCA § 907. Tobacco product standards [21 U.S.C. § 387g]

(a) In general

(1) Special rules

(A) Special rule for cigarettes

[A] cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Nothing in this subparagraph shall be construed to limit the Secretary's authority to take action under this section or other sections of this chapter applicable to menthol or any artificial or natural flavor, herb, or spice not specified in this subparagraph.

. . . .

(3) Tobacco product standards

(A) In general

The Secretary may adopt tobacco product standards in addition to those in paragraph (1) if the Secretary finds that a tobacco product standard is appropriate for the protection of the public health.

(B) Determinations

(i) Considerations

In making a finding described in subparagraph (A), the Secretary shall consider scientific evidence concerning—

(I) the risks and benefits to the population as a whole, including users and nonusers of tobacco products, of the proposed standard;

(II) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(III) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(ii) Additional considerations

In the event that the Secretary makes a determination, set forth in a proposed tobacco product standard in a proposed rule, that it is appropriate for the protection of public health to require the reduction or elimination of an additive, constituent (including a smoke constituent), or other component of a tobacco product because the Secretary has found that the additive, constituent, or other component is or may be harmful, any party objecting to the proposed standard on the ground that the proposed standard will not reduce or eliminate the risk of illness or injury may provide for the Secretary's consideration scientific evidence that

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demonstrates that the proposed standard will not reduce or eliminate the risk of illness or injury.

(4) Content of tobacco product standards

A tobacco product standard established under this section for a tobacco product—

(A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—

(i) for nicotine yields of the product;

(ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or

(iii) relating to any other requirement under subparagraph (B);

(B) shall, where appropriate for the protection of the public health, include—

(i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;

(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;

(iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;

(iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii) show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) a provision requiring that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 906(d);

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

(5) Periodic reevaluation of tobacco product standards

The Secretary shall provide for periodic evaluation of tobacco product standards established under this section to determine whether such standards should be changed to reflect new medical, scientific, or other technological data. The Secretary may provide for testing under paragraph (4)(B) by any person.

. . . .

(c) Proposed standards

(1) In general

The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any tobacco product standard.

. . . .

(d) Promulgation

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(1) In general

After the expiration of the period for comment on a notice of proposed rulemaking . . . and any report from the Tobacco Products Scientific Advisory Committee, the Secretary shall—

(A) if the Secretary determines that the standard would be appropriate for the protection of the public health, promulgate a regulation establishing a tobacco product standard . . . ; or

(B) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination.

(2) Effective date

A regulation establishing a tobacco product standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before 1 year after the date of its publication unless the Secretary determines that an earlier effective date is necessary for the protection of the public health. . . .

(3) Limitation on power granted to the Food and Drug Administration

Because of the importance of a decision of the Secretary to issue a regulation—

(A) banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or

(B) requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this chapter.

(4) Amendment; revocation

(A) Authority

The Secretary, upon the Secretary's own initiative or upon petition of an interested person, may by a regulation, promulgated in accordance with the requirements of subsection (c) and paragraph (2), amend or revoke a tobacco product standard.

. . . .

(5) Referral to Advisory Committee

. . . .

The Secretary may refer a proposed regulation for the establishment, amendment, or revocation of a tobacco product standard to the Tobacco Products Scientific Advisory Committee for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment.

. . . .

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FFDCA § 910. Application for review of certain tobacco products [21 U.S.C. § 387j]

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 905(j); and the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 905(j) within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 905(j), the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

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(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

. . . .

(b) Application

(1) Contents

An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 907 which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

. . . .

(c) Action on application

(1) Deadline

(A) In general

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As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

. . . .

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e);

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 907, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

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(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

. . . .

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

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FFDCA § 911. Modified risk tobacco products [21 U.S.C. § 387k]

(a) In general

No person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product unless an order issued pursuant to subsection (g) is effective with respect to such product.

(b) Definitions

In this section:

(1) Modified risk tobacco product

The term "modified risk tobacco product" means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.

(2) Sold or distributed

(A) In general

With respect to a tobacco product, the term "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" means a tobacco product—

(i) the label, labeling, or advertising of which represents explicitly or implicitly that—

(I) the tobacco product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products;

(II) the tobacco product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or

(III) the tobacco product or its smoke does not contain or is free of a substance;

(ii) the label, labeling, or advertising of which uses the descriptors "light", "mild", or "low" or similar descriptors; or

(iii) the tobacco product manufacturer of which has taken any action directed to consumers through the media or otherwise, other than by means of the tobacco product's label, labeling, or advertising, after June 22, 2009, respecting the product that would be reasonably expected to result in consumers believing that the tobacco product or its smoke may present a lower risk of disease or is less harmful than one or more commercially marketed tobacco products, or presents a reduced exposure to, or does not contain or is free of, a substance or substances.

. . . .

(C) Smokeless tobacco product

No smokeless tobacco product shall be considered to be "sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products" solely because its label, labeling, or advertising uses the following phrases to describe such product and its use: "smokeless tobacco", "smokeless tobacco product", "not consumed by smoking", "does not produce smoke", "smokefree", "smoke-free", "without smoke", "no smoke", or "not smoke".

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. . . .

(c) Tobacco dependence products

A product that is intended to be used for the treatment of tobacco dependence, including smoking cessation, is not a modified risk tobacco product under this section if it has been approved as a drug or device by the Food and Drug Administration and is subject to the requirements of subchapter V.

. . . .

(g) Marketing

(1) Modified risk products

Except as provided in paragraph (2), the Secretary shall, with respect to an application submitted under this section, issue an order that a modified risk product may be commercially marketed only if the Secretary determines that the applicant has demonstrated that such product, as it is actually used by consumers, will—

(A) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and

(B) benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

. . . .

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CHAPTER X—MISCELLANEOUS (§§ 1001-1013)

FFDCA § 1001. Separability clause [21 U.S.C. § 391]

If any provision of this chapter is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the chapter and the applicability thereof to other persons and circumstances shall not be affected thereby.

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FFDCA § 1002. Exemption of meats and meat food products [21 U.S.C. § 392]

(a) Law determinative of exemption

Meats and meat food products shall be exempt from the provisions of this chapter to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended.

(b) Laws unaffected

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of section 351 of the Public Health Service Act (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832-833); the Filled Cheese Act of June 6, 1896 (U.S.C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923; or the Import Milk Act of February 15, 1927.

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FFDCA § 1003. Food & Drug Administration [21 U.S.C. § 393]

(a) In general

There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

(b) Mission

The Administration shall—

(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

(2) with respect to such products, protect the public health by ensuring that—

(A) foods are safe, wholesome, sanitary, and properly labeled;

(B) human and veterinary drugs are safe and effective;

(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

(D) cosmetics are safe and properly labeled; and

(E) public health and safety are protected from electronic product radiation;

(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

. . . .

(d) Commissioner

(1) Appointment

There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the "Commissioner") who shall be appointed by the President by and with the advice and consent of the Senate.

(2) General powers

The Secretary, through the Commissioner, shall be responsible for executing this chapter and for—

(A) providing overall direction to the Food and Drug Administration and establishing and implementing general policies respecting the management and operation of programs and activities of the Food and Drug Administration;

(B) coordinating and overseeing the operation of all administrative entities within the Administration;

(C) research relating to foods, drugs, cosmetics, devices, and tobacco products in carrying out this chapter;

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(D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and

(E) performing such other functions as the Secretary may prescribe.

. . . .

(f) Agency plan for statutory compliance

(1) In general

Not later than 1 year after November 21, 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this chapter. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.

(2) Objectives of agency plan

The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to—

(A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this chapter;

(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

(C) implementing inspection and postmarket monitoring provisions of this chapter;

(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

(E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this chapter for the review of all applications and submissions described in subparagraph (A) and submitted after November 21, 1997; and

(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

(g) Annual report

The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

(2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.

. . . .

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FFDCA § 1006. Practice of medicine [21 U.S.C. § 396]

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

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Administrative Procedure Act (5 U.S.C. §§ 551 et seq.)

5 U.S.C. § 551. Definitions

For the purpose of this subchapter—

(1) "agency" means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

or except as to the requirements of section 552 of this title—

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; subchapter II of chapter 471 of title 49; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix;

(2) "person" includes an individual, partnership, corporation, association, or public or private organization other than an agency;

(3) "party" includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in an agency proceeding, and a person or agency admitted by an agency as a party for limited purposes;

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

(8) "license" includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission;

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(9) "licensing" includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license;

(10) "sanction" includes the whole or a part of an agency—

(A) prohibition, requirement, limitation, or other condition affecting the freedom of a person;

(B) withholding of relief;

(C) imposition of penalty or fine;

(D) destruction, taking, seizure, or withholding of property;

(E) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees;

(F) requirement, revocation, or suspension of a license; or

(G) taking other compulsory or restrictive action;

(11) "relief" includes the whole or a part of an agency—

(A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;

(B) recognition of a claim, right, immunity, privilege, exemption, or exception; or

(C) taking of other action on the application or petition of, and beneficial to, a person;

(12) "agency proceeding" means an agency process as defined by paragraphs (5), (7), and (9) of this section;

(13) "agency action" includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act; and

(14) "ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter.

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5 U.S.C. § 553. Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed;

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved; and

(4) the Internet address of a summary of not more than 100 words in length of the proposed rule, in plain language, that shall be posted on the Internet website under section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as regulations.gov).

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

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5 U.S.C. § 556. Hearings; presiding employees; powers and duties; burden of proof; evidence; record as basis of decision

(a) This section applies, according to the provisions thereof, to hearings required by section 553 or 554 of this title to be conducted in accordance with this section.

(b) There shall preside at the taking of evidence—

(1) the agency;

(2) one or more members of the body which comprises the agency; or

(3) one or more administrative law judges appointed under section 3105 of this title.

This subchapter does not supersede the conduct of specified classes of proceedings, in whole or in part, by or before boards or other employees specially provided for by or designated under statute. . . .

(c) Subject to published rules of the agency and within its powers, employees presiding at hearings may—

(1) administer oaths and affirmations;

(2) issue subpenas authorized by law;

(3) rule on offers of proof and receive relevant evidence;

(4) take depositions or have depositions taken when the ends of justice would be served;

(5) regulate the course of the hearing;

(6) hold conferences for the settlement or simplification of the issues by consent of the parties or by the use of alternative means of dispute resolution as provided in subchapter IV of this chapter;

(7) inform the parties as to the availability of one or more alternative means of dispute resolution, and encourage use of such methods;

(8) require the attendance at any conference held pursuant to paragraph (6) of at least one representative of each party who has authority to negotiate concerning resolution of issues in controversy;

(9) dispose of procedural requests or similar matters;

(10) make or recommend decisions in accordance with section 557 of this title; and

(11) take other action authorized by agency rule consistent with this subchapter.

(d) Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. Any oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence. . . .

(e) The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 . . . .

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5 U.S.C. § 557. Initial decisions; conclusiveness; review by agency; submissions by parties; contents of decisions; record

(a) This section applies, according to the provisions thereof, when a hearing is required to be conducted in accordance with section 556 of this title.

(b) When the agency did not preside at the reception of the evidence, the presiding employee or, in cases not subject to section 554(d) of this title, an employee qualified to preside at hearings pursuant to section 556 of this title, shall initially decide the case unless the agency requires, either in specific cases or by general rule, the entire record to be certified to it for decision. When the presiding employee makes an initial decision, that decision then becomes the decision of the agency without further proceedings unless there is an appeal to, or review on motion of, the agency within time provided by rule. On appeal from or review of the initial decision, the agency has all the powers which it would have in making the initial decision except as it may limit the issues on notice or by rule. When the agency makes the decision without having presided at the reception of the evidence, the presiding employee or an employee qualified to preside at hearings pursuant to section 556 of this title shall first recommend a decision, except that in rule making or determining applications for initial licenses—

(1) instead thereof the agency may issue a tentative decision or one of its responsible employees may recommend a decision; or

(2) this procedure may be omitted in a case in which the agency finds on the record that due and timely execution of its functions imperatively and unavoidably so requires.

(c) Before a recommended, initial, or tentative decision, or a decision on agency review of the decision of subordinate employees, the parties are entitled to a reasonable opportunity to submit for the consideration of the employees participating in the decisions—

(1) proposed findings and conclusions; or

(2) exceptions to the decisions or recommended decisions of subordinate employees or to tentative agency decisions; and

(3) supporting reasons for the exceptions or proposed findings or conclusions.

The record shall show the ruling on each finding, conclusion, or exception presented. All decisions, including initial, recommended, and tentative decisions, are a part of the record and shall include a statement of—

(A) findings and conclusions, and the reasons or basis therefor, on all the material issues of fact, law, or discretion presented on the record; and

(B) the appropriate rule, order, sanction, relief, or denial thereof.

(d)

(1) In any agency proceeding which is subject to subsection (a) of this section, except to the extent required for the disposition of ex parte matters as authorized by law—

(A) no interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is

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or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding;

(B) no member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, shall make or knowingly cause to be made to any interested person outside the agency an ex parte communication relevant to the merits of the proceeding;

(C) a member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of such proceeding who receives, or who makes or knowingly causes to be made, a communication prohibited by this subsection shall place on the public record of the proceeding:

(i) all such written communications;

(ii) memoranda stating the substance of all such oral communications; and

(iii) all written responses, and memoranda stating the substance of all oral responses, to the materials described in clauses (i) and (ii) of this subparagraph;

(D) upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this subsection, the agency, administrative law judge, or other employee presiding at the hearing may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation; and

(E) the prohibitions of this subsection shall apply beginning at such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge.

(2) This subsection does not constitute authority to withhold information from Congress.

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Federal Advisory Committee Act (5 U.S.C. App. 2)

5 U.S.C. App. 2, § 2. Findings and Purpose

(a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed;

(2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary;

(3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established;

(4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees;

(5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and

(6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

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5 U.S.C. App. 2, § 3. Definitions

For the purpose of this Act—

(1) The term "Administrator" means the Administrator of General Services.

(2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is—

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

(C) established or utilized by one or more agencies,

in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes

(i) any committee that is composed wholly of full-time, or permanent part-time, officers or employees of the Federal Government, and

(ii) any committee that is created by the National Academy of Sciences or the National Academy of Public Administration.

. . . .

(4) The term "Presidential advisory committee" means an advisory committee which advises the President.

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5 U.S.C. App. 2, § 8. Responsibilities of agency heads; Advisory Committee Management Officer, designation

(a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency . . . .Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

(2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and

(3) carry out, on behalf of that agency, the provisions of section 552 of title 5, United States Code, with respect to such reports, records, and other papers.

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5 U.S.C. App. 2, § 9. Establishment and purpose of advisory committees; publication in Federal Register; charter: filing, contents, copy

(a) No advisory committee shall be established unless such establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Administrator, with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

(c) No advisory committee shall meet or take any action until an advisory committee charter has been filed with

(1) the Administrator, in the case of Presidential advisory committees, or

(2) with the head of the agency to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency.

Such charter shall contain the following information:

(A) the committee's official designation;

(B) the committee's objectives and the scope of its activity;

(C) the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man-years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

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5 U.S.C. App. 2, § 10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance

(a)

(1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Administrator shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection (c) of section 552b of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

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Fair Packaging and Labeling Act (15 U.S.C. § 1451 et seq.)

15 U.S.C. § 1451. Congressional declaration of policy

Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons. Therefore, it is hereby declared to be the policy of the Congress to assist consumers and manufacturers in reaching these goals in the marketing of consumer goods.

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15 U.S.C. § 1452. Unfair and deceptive packaging and labeling; scope of prohibition

(a) Nonconforming labels

It shall be unlawful for any person engaged in the packaging or labeling of any consumer commodity (as defined in this chapter) for distribution in commerce, or for any person (other than a common carrier for hire, a contract carrier for hire, or a freight forwarder for hire) engaged in the distribution in commerce of any packaged or labeled consumer commodity, to distribute or to cause to be distributed in commerce any such commodity if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to the provisions of this chapter and of regulations promulgated under the authority of this chapter.

(b) Exemptions

The prohibition contained in subsection (a) shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons

(1) are engaged in the packaging or labeling of such commodities, or

(2) prescribe or specify by any means the manner in which such commodities are packaged or labeled.

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15 U.S.C. § 1454. Rules and regulations

(a) Promulgating authority

The authority to promulgate regulations under this chapter is vested in (A) the Secretary of Health and Human Services (referred to hereinafter as the "Secretary") with respect to any consumer commodity which is a food, drug, device, or cosmetic, as each such term is defined by section 321 of Title 21; and (B) the Federal Trade Commission (referred to hereinafter as the "Commission") with respect to any other consumer commodity.

. . . .

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15 U.S.C. § 1456. Enforcement

(a) Misbranded consumer commodities

Any consumer commodity which is a food, drug, device, or cosmetic, as each such term is defined by section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), and which is introduced or delivered for introduction into commerce in violation of any of the provisions of this chapter, or the regulations issued pursuant to this chapter, shall be deemed to be misbranded within the meaning of chapter III of the Federal Food, Drug, and Cosmetic Act, but the provisions of section 303 of that Act (21 U.S.C. 333) shall have no application to any violation of section 1452 of this title.

(b) Unfair or deceptive acts or practices in commerce

Any violation of any of the provisions of this chapter, or the regulations issued pursuant to this chapter, with respect to any consumer commodity which is not a food, drug, device, or cosmetic, shall constitute an unfair or deceptive act or practice in commerce in violation of section 45(a) of this title and shall be subject to enforcement under section 45(b) of this title.

(c) Imports

In the case of any imports into the United States of any consumer commodity covered by this chapter, the provisions of sections 1453 and 1454 of this title shall be enforced by the Secretary of the Treasury pursuant to section 801(a) and (b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381).

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15 U.S.C. § 1459. Definitions

For the purpose of this chapter—

(a) The term "consumer commodity", except as otherwise specifically provided by this subsection, means any food, drug, device, or cosmetic (as those terms are defined by the Federal Food, Drug, and Cosmetic Act), and any other article, product, or commodity of any kind or class which is customarily produced or distributed for sale through retail sales agencies or instrumentalities for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which usually is consumed or expended in the course of such consumption or use. Such term does not include—

(1) any meat or meat product, poultry or poultry product, or tobacco or tobacco product;

(2) any commodity subject to packaging or labeling requirements imposed by the Secretary of Agriculture pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act, or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the Act of March 4, 1913, commonly known as the Virus-Serum-Toxin Act;

(3) any drug subject to the provisions of section 503(b)(1) or 506 of the Federal Food, Drug, and Cosmetic Act;

(4) any beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act; or

(5) any commodity subject to the provisions of the Federal Seed Act.

(b) The term "package" means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include—

(1) shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof;

(2) shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity; or

(3) containers subject to the provisions of the Act of August 3, 1912 (37 Stat. 250, as amended; 15 U.S.C. 231-233), or the Act of March 4, 1915 (38 Stat. 1186, as amended; 15 U.S.C. 234-236).

(c) The term "label" means any written, printed, or graphic matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

(d) The term "person" includes any firm, corporation, or association.

(e) The term "commerce" means

(1) commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, or any territory or possession of the United States, and any place outside thereof, and

(2) commerce within the District of Columbia or within any territory or possession of the United States not organized with a legislative body, but shall not include exports to foreign countries.

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(f) The term "principal display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

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Title 18. Crimes and Criminal Procedure (18 U.S.C. §§ 2 et seq.)

18 U.S.C. § 3571. Sentence of fine

(a) **In general.**—A defendant who has been found guilty of an offense may be sentenced to pay a fine.

(b) **Fines for individuals.**—Except as provided in subsection (e) of this section, an individual who has been found guilty of an offense may be fined not more than the greatest of—

(1) the amount specified in the law setting forth the offense;

(2) the applicable amount under subsection (d) of this section;

(3) for a felony, not more than $250,000;

(4) for a misdemeanor resulting in death, not more than $250,000;

(5) for a Class A misdemeanor that does not result in death, not more than $100,000;

(6) for a Class B or C misdemeanor that does not result in death, not more than $5,000; or

(7) for an infraction, not more than $5,000.

(c) **Fines for organizations**.—Except as provided in subsection (e) of this section, an organization that has been found guilty of an offense may be fined not more than the greatest of—

(1) the amount specified in the law setting forth the offense;

(2) the applicable amount under subsection (d) of this section;

(3) for a felony, not more than $500,000;

(4) for a misdemeanor resulting in death, not more than $500,000;

(5) for a Class A misdemeanor that does not result in death, not more than $200,000;

(6) for a Class B or C misdemeanor that does not result in death, not more than $10,000; and

(7) for an infraction, not more than $10,000.

(d) **Alternative fine based on gain or loss**.—If any person derives pecuniary gain from the offense, or if the offense results in pecuniary loss to a person other than the defendant, the defendant may be fined not more than the greater of twice the gross gain or twice the gross loss, unless imposition of a fine under this subsection would unduly complicate or prolong the sentencing process.

(e) **Special rule for lower fine specified in substantive provision**.—If a law setting forth an offense specifies no fine or a fine that is lower than the fine otherwise applicable under this section and such law, by specific reference, exempts the offense from the applicability of the fine otherwise applicable under this section, the defendant may not be fined more than the amount specified in the law setting forth the offense.

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Virus, Serum, and Toxin Act (21 U.S.C. §§ 151 et seq.)

TITLE 21, CHAPTER 5—VIRUSES, SERUMS, TOXINS, ANTITOXINS AND ANALOGOUS PRODUCTS

21 U.S.C. § 151. Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments

It shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment in or from the United States, the District of Columbia, any territory of the United States, or any place under the jurisdiction of the United States, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized.

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21 U.S.C. § 152. Importation regulated and prohibited

The importation into the United States of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, is prohibited without

(1) a permit from the Secretary of Agriculture, or

(2) in the case of an article originating in Canada, such permit or, in lieu of such permit, such certification by Canada as may be prescribed by the Secretary of Agriculture.

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21 U.S.C. § 153. Inspection of imports; denial of entry and destruction

The Secretary of Agriculture is authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer.

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21 U.S.C. § 154. Regulations for preparation and sale; licenses

The Secretary of Agriculture is authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, or otherwise to carry out this chapter, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid.

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Poultry Products Inspection Act (21 U.S.C. §§ 451 et seq.)

21 U.S.C. § 451. Congressional statement of findings

Poultry and poultry products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that poultry products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded poultry products impair the effective regulation of poultry products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged poultry products, and result in sundry losses to poultry producers and processors of poultry and poultry products, as well as injury to consumers. It is hereby found that all articles and poultry which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

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21 U.S.C. § 452. Congressional declaration of policy

It is hereby declared to be the policy of the Congress to provide for the inspection of poultry and poultry products and otherwise regulate the processing and distribution of such articles as hereinafter prescribed to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded. It is the intent of Congress that when poultry and poultry products are condemned because of disease, the reason for condemnation in such instances shall be supported by scientific fact, information, or criteria, and such condemnation under this chapter shall be achieved through uniform inspection standards and uniform applications thereof.

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21 U.S.C. § 455. Inspection in official establishments

(a) Ante mortem inspection

For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product which is capable of use as human food and is adulterated, the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry in each official establishment processing poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

(b) Post mortem inspection; quarantine, segregation, and reinspection

The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation, and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this chapter.

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21 U.S.C. § 458. Prohibited acts

(a) No person shall—

(1) slaughter any poultry or process any poultry products which are capable of use as human food at any establishment processing any such articles for commerce, except in compliance with the requirements of this chapter;

(2) sell, transport, offer for sale or transportation, or receive for transportation, in commerce,

(A) any poultry products which are capable of use as human food and are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or

(B) any poultry products required to be inspected under this chapter unless they have been so inspected and passed;

(3) do, with respect to any poultry products which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such products to be adulterated or misbranded;

(4) sell, transport, offer for sale or transportation, or receive for transportation, in commerce or from an official establishment, any slaughtered poultry from which the blood, feathers, feet, head, or viscera have not been removed in accordance with regulations promulgated by the Secretary, except as may be authorized by regulations of the Secretary;

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Federal Meat Inspection Act (21 U.S.C. §§ 601 et seq.)

21 U.S.C. § 601. Definitions

As used in this chapter, except as otherwise specified, the following terms shall have the meanings stated below:

(a) The term "Secretary" means the Secretary of Agriculture of the United States or his delegate.

. . . .

(j) The term "meat food product" means any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products. This term as applied to food products of equines shall have a meaning comparable to that provided in this paragraph with respect to cattle, sheep, swine, and goats.

. . . .

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)

(A) if it bears or contains (by reason of administration of any substance to the live animal or otherwise) any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title,

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title,

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title: *Provided*, That an article which is not adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive in or on such article is prohibited by regulations of the Secretary in establishments at which inspection is maintained under this subchapter;

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(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title;

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is; or

(9) if it is margarine containing animal fat and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance.

(n) The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) if its container is so made, formed, or filled as to be misleading;

(5) if in a package or other container unless it bears a label showing

(A) the name and place of business of the manufacturer, packer, or distributor; and

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count:

Provided, That under clause (B) of this subparagraph (5), reasonable variations may be permitted, and exemptions as to small packages may be established, by regulations prescribed by the Secretary;

(6) if any word, statement, or other information required by or under authority of this chapter to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 607 of this title unless

(A) it conforms to such definition and standard, and

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(B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) if it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations of the Secretary under section 607 of this title, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) if it is not subject to the provisions of subparagraph (7), unless its label bears

(A) the common or usual name of the food, if any there be, and

(B) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient;

except that spices, flavorings, and colorings may, when authorized by the Secretary, be designated as spices, flavorings, and colorings without naming each: *Provided*, That to the extent that compliance with the requirements of clause (B) of this subparagraph (9) is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary;

(10) if it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary, after consultation with the Secretary of Health and Human Services, determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses;

(11) if it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact:

Provided, That, to the extent that compliance with the requirements of this subparagraph (11) is impracticable, exemptions shall be established by regulations promulgated by the Secretary; or

(12) if it fails to bear, directly thereon or on its container, as the Secretary may by regulations prescribe, the inspection legend and, unrestricted by any of the foregoing, such other information as the Secretary may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed of the manner of handling required to maintain the article in a wholesome condition.

. . . .

(w) The term "amenable species" means—

(1) those species subject to the provisions of this chapter on the day before November 10, 2005;

(2) all fish of the order Siluriformes; and

(3) any additional species of livestock that the Secretary considers appropriate.

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21 U.S.C. § 602. Congressional statement of findings

Meat and meat food products are an important source of the Nation's total supply of food. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged. Unwholesome, adulterated, or misbranded meat or meat food products impair the effective regulation of meat and meat food products in interstate or foreign commerce, are injurious to the public welfare, destroy markets for wholesome, not adulterated, and properly labeled and packaged meat and meat food products, and result in sundry losses to livestock producers and processors of meat and meat food products, as well as injury to consumers. The unwholesome, adulterated, mislabeled, or deceptively packaged articles can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged articles, to the detriment of consumers and the public generally. It is hereby found that all articles and animals which are regulated under this chapter are either in interstate or foreign commerce or substantially affect such commerce, and that regulation by the Secretary and cooperation by the States and other jurisdictions as contemplated by this chapter are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

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21 U.SC. § 603. Examination of animals prior to slaughter; use of humane methods

(a) Examination of animals before slaughtering; diseased animals slaughtered separately and carcasses examined

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

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21 U.SC. § 604. Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection

For the purposes hereinbefore set forth the Secretary shall cause to be made by inspectors appointed for that purpose a post mortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in any State, Territory, or the District of Columbia as articles of commerce which are capable of use as human food; and the carcasses and parts thereof of all such animals found to be not adulterated shall be marked, stamped, tagged, or labeled as "Inspected and passed"; and said inspectors shall label, mark, stamp, or tag as "Inspected and condemned" all carcasses and parts thereof of animals found to be adulterated; and all carcasses and parts thereof thus inspected and condemned shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any such establishment which fails to so destroy any such condemned carcass or part thereof, and said inspectors, after said first inspection, shall, when they deem it necessary, reinspect said carcasses or parts thereof to determine whether since the first inspection the same have become adulterated, and if any carcass or any part thereof shall, upon examination and inspection subsequent to the first examination and inspection, be found to be adulterated, it shall be destroyed for food purposes by the said establishment in the presence of an inspector, and the Secretary may remove inspectors from any establishment which fails to so destroy any such condemned carcass or part thereof.

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21 U.S.C. § 610. Prohibited acts

No person, firm, or corporation shall, with respect to any cattle, sheep, swine, goats, horses, mules, or other equines, or any carcasses, parts of carcasses, meat or meat food products of any such animals—

(a) Slaughtering animals or preparation of articles capable of use as human food

slaughter any such animals or prepare any such articles which are capable of use as human food at any establishment preparing any such articles for commerce, except in compliance with the requirements of this chapter;

(b) Humane methods of slaughter

slaughter or handle in connection with slaughter any such animals in any manner not in accordance with the Act of August 27, 1958 (72 Stat. 862; 7 U.S.C. 1901-1906);

(c) Sales, transportation, and other transactions

sell, transport, offer for sale or transportation, or receive for transportation, in commerce,

(1) any such articles which

(A) are capable of use as human food and

(B) are adulterated or misbranded at the time of such sale, transportation, offer for sale or transportation, or receipt for transportation; or

(2) any articles required to be inspected under this subchapter unless they have been so inspected and passed;

(d) Adulteration or misbranding

do, with respect to any such articles which are capable of use as human food, any act while they are being transported in commerce or held for sale after such transportation, which is intended to cause or has the effect of causing such articles to be adulterated or misbranded.

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21 U.S.C. § 661. Federal and state cooperation

(a) Congressional statement of policy

It is the policy of the Congress to protect the consuming public from meat and meat food products that are adulterated or misbranded and to assist in efforts by State and other Government agencies to accomplish this objective. In furtherance of this policy—

(1) Development and administration of State meat inspection program equal to subchapter I ante and post mortem inspection, reinspection, and sanitation requirements

The Secretary is authorized, whenever he determines that it would effectuate the purposes of this chapter, to cooperate with the appropriate State agency in developing and administering a State meat inspection program in any State which has enacted a State meat inspection law that imposes mandatory ante mortem and post mortem inspection, reinspection and sanitation requirements that are at least equal to those under subchapter I of this chapter, with respect to all or certain classes of persons engaged in the State in slaughtering cattle, sheep, swine, goats, or equines, or preparing the carcasses, parts thereof, meat or meat food products, of any such animals for use as human food solely for distribution within such State.

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Egg Products Inspection Act (21 U.S.C. §§ 1031 et seq.)

21 U.S.C. § 1031. Congressional statement of findings

Eggs and egg products are an important source of the Nation's total supply of food, and are used in food in various forms. They are consumed throughout the Nation and the major portion thereof moves in interstate or foreign commerce. It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures prescribed herein for assuring that eggs and egg products distributed to them and used in products consumed by them are wholesome, otherwise not adulterated, and properly labeled and packaged. Lack of effective regulation for the handling or disposition of unwholesome, otherwise adulterated, or improperly labeled or packaged egg products and certain qualities of eggs is injurious to the public welfare and destroys markets for wholesome, not adulterated, and properly labeled and packaged eggs and egg products and results in sundry losses to producers and processors, as well as injury to consumers. Unwholesome, otherwise adulterated, or improperly labeled or packaged products can be sold at lower prices and compete unfairly with the wholesome, not adulterated, and properly labeled and packaged products, to the detriment of consumers and the public generally. It is hereby found that all egg products and the qualities of eggs which are regulated under this chapter are either in interstate or foreign commerce, or substantially affect such commerce, and that regulation by the Secretary of Agriculture and the Secretary of Health and Human Services, and cooperation by the States and other jurisdictions, as contemplated by this chapter, are appropriate to prevent and eliminate burdens upon such commerce, to effectively regulate such commerce, and to protect the health and welfare of consumers.

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21 U.S.C. § 1032. Congressional declaration of policy

It is hereby declared to be the policy of the Congress to provide for the inspection of certain egg products, restrictions upon the disposition of certain qualities of eggs, and uniformity of standards for eggs, and otherwise regulate the processing and distribution of eggs and egg products as hereinafter prescribed to prevent the movement or sale for human food, of eggs and egg products which are adulterated or misbranded or otherwise in violation of this chapter.

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21 U.S.C. § 1033. Definitions

For purposes of this chapter—

(a) The term "adulterated" applies to any egg or egg product under one or more of the following circumstances—

(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2)

(A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which may, in the judgment of the Secretary, make such article unfit for human food;

(B) if it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 346a of this title;

(C) if it bears or contains any food additive which is unsafe within the meaning of section 348 of this title;

(D) if it bears or contains any color additive which is unsafe within the meaning of section 379e of this title:

Provided, That an article which is not otherwise deemed adulterated under clause (B), (C), or (D) shall nevertheless be deemed adulterated if use of the pesticide chemical, food additive, or color additive, in or on such article, is prohibited by regulations of the Secretary in official plants;

(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for human food;

(4) if it has been prepared, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) if it is an egg which has been subjected to incubation or the product of any egg which has been subjected to incubation;

(6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title; or

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

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(f) The term "egg product" means any dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products.

(g) The term "egg" means the shell egg of the domesticated chicken, turkey, duck, goose, or guinea.

. . . .

(l) The term "misbranded" shall apply to egg products which are not labeled and packaged in accordance with the requirements prescribed by regulations of the Secretary under section 1036 of this title.

. . . .

(u) The terms "pesticide chemical," "food additive," "color additive," and "raw agricultural commodity" shall have the same meaning for purposes of this chapter as under the Federal Food, Drug, and Cosmetic Act.

. . . .

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21 U.S.C. § 1037. Prohibited acts

(a)

(1) No person shall buy, sell, or transport, or offer to buy or sell, or offer or receive for transportation, in any business in commerce any restricted eggs, capable of use as human food, except as authorized by regulations of the Secretary under such conditions as he may prescribe to assure that only eggs fit for human food are used for such purpose.

(2) No egg handler shall possess with intent to use, or use, any restricted eggs in the preparation of human food for commerce except that such eggs may be so possessed and used when authorized by regulations of the Secretary under such conditions as he may prescribe to assure that only eggs fit for human food are used for such purpose.

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Title 35, Chapter 28—Infringement of Patents (35 U.S.C. §§ 271 et seq.)

35 U.S.C. § 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

. . . .

(e)

(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the [Virus, Serum, and Toxin Act]) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit—

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the [Virus, Serum, and Toxin Act] (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)

(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

. . . .

(4) For an act of infringement described in paragraph (2)—

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(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person . . . for a declaratory judgment that such patent is invalid or not infringed.

(6)

(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

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(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

. . . .

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Public Health Services Act (42 U.S.C. §§ 201 et seq.)

PHSA § 351. Regulation of biological products [42 U.S.C. § 262]

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and

(B) each package of the biological product is plainly marked with—

(i) the proper name of the biological product contained in the package;

(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

(iii) the expiration date of the biological product.

(2)

(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

. . . .

(C) The Secretary shall approve a biologics license application—

(i) on the basis of a demonstration that—

(I) the biological product that is the subject of the application is safe, pure, and potent; and

(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c) of this section.

(D) Postmarket studies and clinical trials; labeling; risk evaluation and mitigation strategy

A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505-1 of the Federal Food, Drug, and Cosmetic Act.

. . . .

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

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No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of Title 5.

(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. . . .

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act.

. . . .

(i) "Biological product" defined

In this section:

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity'', in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be

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substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act, including the requirements under sections 505(o), 505(p), and 505-1 of such Act, applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc)); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

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(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

. . . .

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

. . . .

(6) Exclusivity for first interchangeable biological product

The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which

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a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)

(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken, and the term "first interchangeable biosimilar biological product" means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

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(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

. . . .

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

. . . .

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

. . . .

(9) Public listing

(A) In general

(i) Initial publication

Not later than 180 days after December 27, 2020, the Secretary shall publish and make available to the public in a searchable, electronic format—

(I) a list of each biological product, by nonproprietary name (proper name), for which, as of December 27, 2020, a biologics license under subsection (a) or this subsection is in effect, or that, as of such date of enactment, is deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009;

(II) the date of licensure of the marketing application and the application number; and

(III) with respect to each biological product described in subclause (I), the licensure status, and, as available, the marketing status.

. . . .

(iv) Listing of exclusivities

For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period under paragraph (6) or paragraph (7) for which the Secretary has determined such biological product to be eligible and that has not concluded.

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(l) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

. . . .

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

. . . .

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PHSA § 361. Regulations to control communicable diseases [42 U.S.C. § 264]

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General[].

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) Apprehension and examination of persons reasonably believed to be infected

(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and

(A) to be moving or about to move from a State to another State; or

(B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State.

Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term "qualifying stage', with respect to a communicable disease, means that such disease

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Preemption

Nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including

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provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 266 of this title.

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CODE OF FEDERAL REGULATIONS

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Title 9. Animals and Animal Products

Part 101—Definitions

§ 101.2 Administrative terminology.

The following administrative words and phrases shall mean:

. . . .

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

. . . .

Biological products. The term biological products, also referred to in this subchapter as biologics, biologicals, or products, shall mean all viruses, serums, toxins (excluding substances that are selectively toxic to microorganisms, e.g., antibiotics), or analogous products at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. The term "biological products" includes but is not limited to vaccines, bacterins, allergens, antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live organisms, and diagnostic components, that are of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens, or antibodies.

(1) A product's intended use shall be determined through an objective standard and not a subjective one, and would be dependent on factors such as representations, claims (either oral or written), packaging, labeling, or appearance.

(2) The term analogous products shall include:

(i) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals and which are similar in function to biological products in that they act, or are intended to act, through the stimulation, supplementation, enhancement, or modulation of the immune system or immune response; or

(ii) Substances, at any stage of production, shipment, distribution, or sale, which are intended for use in the treatment of animals through the detection or measurement of antigens, antibodies, nucleic acids, or immunity; or

(iii) Substances, at any stage of production, shipment, distribution, or sale, which resemble or are represented as biological products intended for use in the treatment of animals through appearance, packaging, labeling, claims (either oral or written), representations, or through any other means.

(3) The term treatment shall mean the prevention, diagnosis, management, or cure of diseases of animals.

. . . .

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Virus-Serum-Toxin Act. The Act of March 4, 1913, 37 Stat. 832-833; as amended December 23, 1985, Public Law 99-198, 99 Stat. 1654-1655; and as further amended September 28, 1988, Public Law 100-449, 102 Stat. 1868; 21 U.S.C. 151-159.

U.S. Veterinary Biological Product License. A document, sometimes referred to as a product license, which is issued pursuant to part 102 of this subchapter to the holder of an establishment license, as a part of and ancillary to the establishment license, and which authorizes production of a specified biological product in the designated licensed establishment.

U.S. Veterinary Biological Product Permit. A document, sometimes referred to as a permit, issued to a person authorizing the importation of specified biological products subject to restrictions and controls as provided in the regulations.

U.S. Veterinary Biologics Establishment License. A document referred to as an establishment license, which is issued pursuant to part 102 of this subchapter, authorizing the use of designated premises for production of biological products specified in one or more unexpired, unsuspended, and unrevoked product license(s).

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Part 102—Licenses for biological products

§ 102.1 Licenses issued by the Administrator.

Each establishment qualified to prepare biological products under the Virus-Serum-Toxin Act shall hold an unexpired and unrevoked U.S. Veterinary Biologics Establishment License issued by the Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment unless the product is subject to the provisions of 9 CFR parts 103 or 106 of this subchapter.

. . . .

§ 102.2 Licenses required.

(a) Every person who prepares biological products subject to the Virus-Serum-Toxin Act shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biologics Establishment License and at least one unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License issued by the Administrator to prepare a biological product.

(b) An applicant who applies for an establishment license must also apply for at least one product license. An establishment license will not be issued without a license authorizing the production of a biological product in the establishment.

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Title 21. Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER A—GENERAL

Part 3—Product jurisdiction

§ 3.1 Purpose.

This regulation relates to agency management and organization and has two purposes. The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101-629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250), by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological. This determination will eliminate, in most cases, the need to receive approvals from more than one FDA component for such combination products. The second purpose of this regulation is to enhance the efficiency of agency management and operations by providing procedures for determining which agency component will have primary jurisdiction for any drug, device, or biological product where such jurisdiction is unclear or in dispute. Nothing in this section prevents FDA from using any agency resources it deems necessary to ensure adequate review of the safety and effectiveness of any product, or the substantial equivalence of any device to a predicate device.

§ 3.2 Definitions.

For the purpose of this part:

(e) Combination product includes:

(1) A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(2) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;

(3) A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product

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would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or

(4) Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

. . . .

§ 3.3 Scope.

This section applies to:

(a) Any combination product, or

(b) Any product where the agency component with primary jurisdiction is unclear or in dispute.

§ 3.4 Designated agency component.

(a) To designate the agency component with primary jurisdiction for the premarket review and regulation of a combination product, the agency shall determine the primary mode of action of the product. Where the primary mode of action is that of:

(1) A drug (other than a biological product), the agency component charged with premarket review of drugs shall have primary jurisdiction;

(2) A device, the agency component charged with premarket review of devices shall have primary jurisdiction;

(3) A biological product, the agency component charged with premarket review of biological products shall have primary jurisdiction.

(b) In some situations, it is not possible to determine, with reasonable certainty, which one mode of action will provide a greater contribution than any other mode of action to the overall therapeutic effects of the combination product. In such a case, the agency will assign the combination product to the agency component that regulates other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole. When there are no other combination products that present similar questions of safety and effectiveness with regard to the combination product as a whole, the agency will assign the combination product to the agency component with the most expertise related to the most significant safety and effectiveness questions presented by the combination product.

(c) The designation of one agency component as having primary jurisdiction for the premarket review and regulation of a combination product does not preclude consultations by that component with other agency components or, in appropriate cases, the requirement by FDA of separate applications.

. . . .

§ 3.5 Procedures for identifying the designated agency component.

(a)

(1) The Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research have entered into agreements clarifying product jurisdictional issues. These guidance documents are on display in the Dockets Management Staff (HFA-

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305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are entitled "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health;" "Intercenter Agreement Between the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research;" "Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research." The availability of any amendments to these intercenter agreements will be announced by FEDERAL REGISTER notice.

(2) These guidance documents describe the allocation of responsibility for categories of products or specific products. These intercenter agreements, and any amendments thereto, are nonbinding determinations designed to provide useful guidance to the public.

(3) The sponsor of a premarket application or required investigational filing for a combination or other product covered by these guidance documents may contact the designated agency component identified in the intercenter agreement before submitting an application of premarket review or to confirm coverage and to discuss the application process.

(b) For a combination product not covered by a guidance document or for a product where the agency component with primary jurisdiction is unclear or in dispute, the sponsor of an application for premarket review should follow the procedures set forth in §3.7 to request a designation of the agency component with primary jurisdiction before submitting the application.

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Part 4—Regulation of combination products

Subpart A—Current Good Manufacturing Practice Requirements for Combination Products

§ 4.1 What is the scope of this subpart?

This subpart applies to combination products. It establishes which current good manufacturing practice requirements apply to these products. This subpart clarifies the application of current good manufacturing practice regulations to combination products, and provides a regulatory framework for designing and implementing the current good manufacturing practice operating system at facilities that manufacture co-packaged or single-entity combination products.

§ 4.2 How does FDA define key terms and phrases in this subpart?

The terms listed in this section have the following meanings for purposes of this subpart:

. . . .

Combination product has the meaning set forth in §3.2(e) of this chapter.

. . . .

§ 4.3 What current good manufacturing practice requirements apply to my combination product?

If you manufacture a combination product, the requirements listed in this section apply as follows:

(a) The current good manufacturing practice requirements in parts 210 and 211 of this chapter apply to a combination product that includes a drug constituent part;

(b) The current good manufacturing practice requirements in part 820 of this chapter apply to a combination product that includes a device constituent part;

(c) The current good manufacturing practice requirements among the requirements (including standards) for biological products in parts 600 through 680 of this chapter apply to a combination product that includes a biological product constituent part to which those requirements would apply if that constituent part were not part of a combination product; and

(d) The current good tissue practice requirements including donor eligibility requirements for HCT/Ps in part 1271 of this chapter apply to a combination product that includes an HCT/P.

Subpart B—Postmarketing Safety Reporting for Combination Products

§ 4.100 What is the scope of this subpart?

(a) This subpart identifies postmarketing safety reporting requirements for combination product applicants and constituent part applicants.

(b) This subpart does not apply to investigational combination products, combination products that have not received marketing authorization, or to persons other than combination product applicants and constituent part applicants.

(c) This subpart supplements and does not supersede other provisions of this chapter, including the provisions in parts 314, 600, 606, 803, and 806 of this chapter, unless a regulation explicitly provides otherwise.

§ 4.102 What reports must you submit to FDA for your combination product or constituent part?

(a) *In general.* If you are a constituent part applicant, the reporting requirements applicable to you that are identified in this section apply to your constituent part, and if you are a combination product applicant,

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the reporting requirements applicable to you that are identified in this section apply to your combination product as a whole.

. . . .

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Part 10—Administrative practices and procedures

§ 10.115 Good Guidance Practices

. . . .

(d) *Are you or FDA required to follow a guidance document*?

(1) No. Guidance documents do not establish legally enforceable rights or responsibilities. They do not legally bind the public or FDA.

(2) You may choose to use an approach other than the one set forth in a guidance document. However, your alternative approach must comply with the relevant statutes and regulations. FDA is willing to discuss an alternative approach with you to ensure that it complies with the relevant statutes and regulations.

(3) Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence.

(e) *Can FDA use means other than a guidance document to communicate new agency policy or a new regulatory approach to a broad public audience?*

The agency may not use documents or other means of communication that are excluded from the definition of guidance document to informally communicate new or different regulatory expectations to a broad public audience for the first time. These GGP's must be followed whenever regulatory expectations that are not readily apparent from the statute or regulations are first communicated to a broad public audience.

. . . .

(i) *What standard elements must FDA include in a guidance document*?

(1) A guidance document must:

(i) Include the term "guidance,"

(ii) Identify the center(s) or office(s) issuing the document,

(iii) Identify the activity to which and the people to whom the document applies,

(iv) Prominently display a statement of the document's nonbinding effect,

(v) Include the date of issuance,

(vi) Note if it is a revision to a previously issued guidance and identify the document that it replaces, and

(vii) Contain the word "draft" if the document is a draft guidance.

(2) Guidance documents must not include mandatory language such as "shall," "must," "required," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

(3) When issuing draft guidance documents that are the product of international negotiations (e.g., guidances resulting from the International Conference on Harmonisation), FDA need not apply paragraphs (i)(1) and (i)(2) of this section. However, any final guidance document issued according to this provision must contain the elements in paragraphs (i)(1) and (i)(2) of this section. . . .

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Part 50—Protection of human subjects

Subpart A—General Provisions

§ 50.1 Scope.

(a) This part applies to all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Additional specific obligations and commitments of, and standards of conduct for, persons who sponsor or monitor clinical investigations involving particular test articles may also be found in other parts (e.g., parts 312 and 812). Compliance with these parts is intended to protect the rights and safety of subjects involved in investigations filed with the Food and Drug Administration pursuant to sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 50.3 Definitions.

As used in this part:

. . . .

(b) *Application for research or marketing permit* includes:

(1) A color additive petition, described in part 71.

(2) A food additive petition, described in parts 171 and 571.

(3) Data and information about a substance submitted as part of the procedures for establishing that the substance is generally recognized as safe for use that results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§170.30 and 570.30.

(4) Data and information about a food additive submitted as part of the procedures for food additives permitted to be used on an interim basis pending additional study, described in §180.1.

(5) Data and information about a substance submitted as part of the procedures for establishing a tolerance for unavoidable contaminants in food and food-packaging materials, described in section 406 of the act.

(6) An investigational new drug application, described in part 312 of this chapter.

(7) A new drug application, described in part 314.

(8) Data and information about the bioavailability or bioequivalence of drugs for human use submitted as part of the procedures for issuing, amending, or repealing a bioequivalence requirement, described in part 320.

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(9) Data and information about an over-the-counter drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in part 330.

(10) Data and information about a prescription drug for human use submitted as part of the procedures for classifying these drugs as generally recognized as safe and effective and not misbranded, described in this chapter.

(11) [Reserved]

(12) An application for a biologics license, described in part 601 of this chapter.

(13) Data and information about a biological product submitted as part of the procedures for determining that licensed biological products are safe and effective and not misbranded, described in part 601.

(14) Data and information about an in vitro diagnostic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in part 809.

(15) An Application for an Investigational Device Exemption, described in part 812.

(16) Data and information about a medical device submitted as part of the procedures for classifying these devices, described in section 513.

(17) Data and information about a medical device submitted as part of the procedures for establishing, amending, or repealing a standard for these devices, described in section 514.

(18) An application for premarket approval of a medical device, described in section 515.

(19) A product development protocol for a medical device, described in section 515.

(20) Data and information about an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for these products, described in section 358 of the Public Health Service Act.

(21) Data and information about an electronic product submitted as part of the procedures for obtaining a variance from any electronic product performance standard, as described in §1010.4.

(22) Data and information about an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from a radiation safety performance standard, as described in §1010.5.

(23) Data and information about a clinical study of an infant formula when submitted as part of an infant formula notification under section 412(c) of the Federal Food, Drug, and Cosmetic Act.

(24) Data and information submitted in a petition for a nutrient content claim, described in §101.69 of this chapter, or for a health claim, described in §101.70 of this chapter.

(25) Data and information from investigations involving children submitted in a new dietary ingredient notification, described in §190.6 of this chapter.

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug

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Administration as part of an application for a research or marketing permit. The term does not include experiments that are subject to the provisions of part 58 of this chapter, regarding nonclinical laboratory studies.

(d) *Investigator* means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

(e) *Sponsor* means a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.

(f) *Sponsor-investigator* means an individual who both initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.

(g) *Human subject* means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient.

(h) *Institution means* any public or private entity or agency (including Federal, State, and other agencies). The word facility as used in section 520(g) of the act is deemed to be synonymous with the term institution for purposes of this part.

(i) *Institutional review board (IRB)* means any board, committee, or other group formally designated by an institution to review biomedical research involving humans as subjects, to approve the initiation of and conduct periodic review of such research. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the act.

. . . .

Subpart B—Informed Consent of Human Subjects

§ 50.20 General requirements for informed consent.

Except as provided in §§ 50.22, 50.23, and 50.24, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

§ 50.22 Exception from informed consent requirements for minimal risk clinical investigations.

The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve an informed consent procedure that does not include or that alters some or all

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of the elements of informed consent set forth in § 50.25(a) and (b), or may waive the requirement to obtain informed consent, provided the IRB finds and documents the following:

(a) The clinical investigation involves no more than minimal risk to the subjects;

(b) The clinical investigation could not practicably be carried out without the requested waiver or alteration;

(c) If the clinical investigation involves using identifiable private information or identifiable biospecimens, the clinical investigation could not practicably be carried out without using such information or biospecimens in an identifiable format;

(d) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

(e) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

§ 50.23 Exception from general requirements.

(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article.

(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.

(3) Time is not sufficient to obtain consent from the subject's legal representative.

(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.

(c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the IRB within 5 working days after the use of the test article.

(d)

(1) Under 10 U.S.C. 1107(f) the President may waive the prior consent requirement for the administration of an investigational new drug to a member of the armed forces in connection with the member's participation in a particular military operation. . . .

[substantial further requirements for such presidential waiver are omitted here]

§ 50.24 Exception from informed consent requirements for emergency research.

(a) The IRB responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of

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or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

(1) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

[substantial further requirements for such emergency research are omitted here]

. . . .

§ 50.27 Documentation of informed consent.

(a) Except as provided in §56.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

. . . .

Subpart D—Additional Safeguards for Children in Clinical Investigations

§ 50.50 IRB duties.

In addition to other responsibilities assigned to IRBs under this part and part 56 of this chapter, each IRB must review clinical investigations involving children as subjects covered by this subpart D and approve only those clinical investigations that satisfy the criteria described in §50.51, §50.52, or §50.53 and the conditions of all other applicable sections of this subpart D.

. . . .

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Part 56—Institutional review boards

Subpart A—General Provisions

§ 56.101 Scope.

(a) This part contains the general standards for the composition, operation, and responsibility of an Institutional Review Board (IRB) that reviews clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with this part is intended to protect the rights and welfare of human subjects involved in such investigations.

. . . .

§ 56.102 Definitions.

As used in this part:

. . . .

(c) *Clinical investigation* means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The term does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies. The terms *research*, *clinical research*, *clinical study*, *study*, and *clinical investigation* are deemed to be synonymous for purposes of this part.

(g) *Institutional Review Board (IRB)* means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects. The term has the same meaning as the phrase institutional review committee as used in section 520(g) of the act.

. . . .

(m) *IRB approval* means the determination of the IRB that the clinical investigation has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

§ 56.103 Circumstances in which IRB review is required.

(a) Except as provided in §§56.104 and 56.105, any clinical investigation which must meet the requirements for prior submission (as required in parts 312, 812, and 813) to the Food and Drug Administration shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of this part.

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(b) Except as provided in §§56.104 and 56.105, the Food and Drug Administration may decide not to consider in support of an application for a research or marketing permit any data or information that has been derived from a clinical investigation that has not been approved by, and that was not subject to initial and continuing review by, an IRB meeting the requirements of this part. The determination that a clinical investigation may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulations to submit the results of the investigation to the Food and Drug Administration.

(c) Compliance with these regulations will in no way render inapplicable pertinent Federal, State, or local laws or regulations.

§ 56.104 Exemptions from IRB requirement.

The following categories of clinical investigations are exempt from the requirements of this part for IRB review:

(a) Any investigation which commenced before July 27, 1981 and was subject to requirements for IRB review under FDA regulations before that date, provided that the investigation remains subject to review of an IRB which meets the FDA requirements in effect before July 27, 1981.

(b) Any investigation commenced before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

(c) Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

(d) Taste and food quality evaluations and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural, chemical, or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

§ 56.105 Waiver of IRB requirement.

On the application of a sponsor or sponsor-investigator, the Food and Drug Administration may waive any of the requirements contained in these regulations, including the requirements for IRB review, for specific research activities or for classes of research activities, otherwise covered by these regulations.

Subpart B—Organization and Personnel

§ 56.106 Registration.

(a) Who must register? Each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the act and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products must register at a site maintained by the Department of Health and Human Services (HHS). (A research permit under section 505(i) of the act is usually known as an investigational new drug application (IND), while a research permit under section 520(g) of the act is usually known as an investigational device exemption (IDE).) An individual authorized to act on the IRB's behalf must submit the registration information. All other IRBs may register voluntarily.

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§ 56.107 IRB membership.

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * * The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.

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Subpart C—IRB Functions and Operations

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§ 56.109 IRB review of research.

(a) An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by these regulations.

(b) An IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25. The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

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(e) An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. . . .

§ 56.111 Criteria for IRB approval of research.

(a) In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

(i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

(ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

(2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The

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IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with and to the extent required by part 50.

(5) Informed consent will be appropriately documented, in accordance with and to the extent required by §50.27.

(6) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(7) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(b) When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects.

(c) In order to approve research in which some or all of the subjects are children, an IRB must determine that all research is in compliance with part 50, subpart D of this chapter.

§ 56.112 Review by institution.

Research covered by these regulations that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

§ 56.114 Cooperative research.

In complying with these regulations, institutions involved in multi-institutional studies may use joint review, reliance upon the review of another qualified IRB, or similar arrangements aimed at avoidance of duplication of effort.

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Part 58—Good laboratory practices for nonclinical laboratory studies

Subpart A—General Provisions

§ 58.1 Scope.

(a) This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 510, 512-516, 518-520, 721, and 801 of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

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§ 58.10 Applicability to studies performed under grants and contracts.

When a sponsor conducting a nonclinical laboratory study intended to be submitted to or reviewed by the Food and Drug Administration utilizes the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, it shall notify the consulting laboratory, contractor, or grantee that the service is part of a nonclinical laboratory study that must be conducted in compliance with the provisions of this part.

§ 58.15 Inspection of a testing facility.

(a) A testing facility shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies within the scope of this part. The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken.

(b) The Food and Drug Administration will not consider a nonclinical laboratory study in support of an application for a research or marketing permit if the testing facility refuses to permit inspection. . . .

Subpart B—Organization and Personnel

§ 58.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

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§ 58.31 Testing facility management.

For each nonclinical laboratory study, testing facility management shall:

(a) Designate a study director as described in §58.33, before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study.

(c) Assure that there is a quality assurance unit as described in §58.35.

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(d) Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

Subpart C—Facilities

§ 58.41 General.

Each testing facility shall be of suitable size and construction to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

Subpart E—Testing Facilities Operation

§ 58.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Animal room preparation.

(2) Animal care.

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles.

(4) Test system observations.

(5) Laboratory tests.

(6) Handling of animals found moribund or dead during study.

(7) Necropsy of animals or postmortem examination of animals.

(8) Collection and identification of specimens.

(9) Histopathology.

(10) Data handling, storage, and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of animals.

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed. Published literature may be used as a supplement to standard operating procedures.

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(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

Subpart F—Test and Control Articles

§ 58.105 Test and control article characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented. Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. In those cases where marketed products are used as control articles, such products will be characterized by their labeling.

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Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. . . .

Subpart J—Records and Reports

§58.185 Reporting of nonclinical laboratory study results.

(a) A final report shall be prepared for each nonclinical laboratory study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and completed.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics.

. . . .

(6) A description of the methods used.

(7) A description of the test system used. . . .

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

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(b) The final report shall be signed and dated by the study director.

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(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible.

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Part 70—Color Additives

§ 70.3. Definitions

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(f) A *color additive* is any material, not exempted under section 201(t) of the act, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. Substances capable of imparting a color to a container for foods, drugs, or cosmetics are not color additives unless the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the transmittal of the color to the contents of the package or any part thereof. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as *color additives*; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a *color additive*. Food ingredients as authorized by a definitions and standard of identity prescribed by regulations pursuant to section 401 of the act are *color additives*, where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed whose intended function is to impart, through the biological processes of the animal, a color to the meat, milk, or eggs of the animal is a color additive and is not exempt from the requirements of the statute. This definition shall apply whether or not such ingredient has nutritive or other functions in addition to the property of imparting color. An ingested drug the intended function of which is to impart color to the human body is a color additive. For the purposes of this part, the term *color* includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not *color additives*.

(g) For a material otherwise meeting the definition of *color additive* to be exempt from section 721 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

(h) The exemption that applies to a pesticide chemical, soil or plant nutrient, or other agricultural chemical, where its coloring effect results solely from its aiding, retarding, or otherwise affecting directly or indirectly, the growth or other natural physiological processes of produce of the soil, applies only to color developed in such product through natural physiological processes such as enzymatic action. If the pesticide chemical, soil or plant nutrient, or other agricultural chemical itself acts as a color or carries as an ingredient a color, and because of this property colors the produce of the soil, it is a *color additive* and is not exempt.

(i) *Safe* means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

(j) The term *straight color* means a color additive listed in parts 73, 74, and 81 of this chapter, and includes lakes and such substances as are permitted by the specifications for such color.

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(k) The term *mixture* means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(l) The term *lake* means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.

(m) The term *diluent* means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein to facilitate the use of the mixture in coloring foods, drugs, or cosmetics or in coloring the human body. The diluent may serve another functional purpose in the foods, drugs, or cosmetics, as for example sweetening, flavoring, emulsifying, or stabilizing, or may be a functional component of an article intended for coloring the human body.

(n) The term *substratum* means the substance on which the pure color in a lake is extended.

(o) The term *pure color* means the color contained in a color additive, exclusive of any intermediate or other component, or of any diluent or substratum contained therein.

(p) The term *batch* means a homogeneous lot of color additive or color additive mixture produced by an identified production operation, which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(q) The term *batch number* means the number assigned to a batch by the person who requests certification thereof.

(r) The term *lot number* means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(s) The term *area of the eye* means the area enclosed with in the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(t) The term *package* means the immediate container in which a color additive or color additive mixture has been packed for shipment or delivery. If the package is then packed in a shipping carton or other protective container, such container shall not be considered to be the immediate container. In the case of color additive mixtures for household use containing less than 15 percent pure color, when two or more containers of 3 ounces each or less, each containing a different color, are distributed as a unit, the immediate container for such unit shall be considered to be the package as defined in this section.

(u) The *hair dye* exemption in section 601(a) of the act applies to coal tar hair dyes intended for use in altering the color of the hair and which are, or which bear or contain, color additives derived from coal tar with the sensitization potential of causing skin irritation in certain individuals and possible blindness when used for dyeing the eyelashes or eyebrows. The exemption is permitted with the condition that the label of any such article bear conspicuously the statutory caution and adequate directions for preliminary patch-testing. The exemption does not apply to coloring ingredients in hair dyes not derived from coal tar, and it does not extend to poisonous or deleterious diluents that may be introduced as wetting agents, hair conditions, emulsifiers, or other components in a color shampoo, rinse, tint, or similar dual-purpose cosmetic that alter the color of the hair.

(v) The terms *externally applied drugs* and *externally applied cosmetics* mean drugs or cosmetics applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

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§ 70.40 Safety factors to be considered.

In accordance with section 721(b)(5)(A)(iii) of the act, the following safety factor will be applied in determining whether the proposed use of a color additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor of 100 to 1 will be used in applying animal experimentation data to man; that is, a color additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals tested. The various species of experimental animals used in the tests shall conform to good pharmacological practice.

§ 70.42 Criteria for evaluating the safety of color additives.

(a) In deciding whether a petition is complete and suitable for filing and in reaching a decision on any petition filed, the Commissioner will apply the "safe-for-use" principle. This will require the presentation of all needed scientific data in support of a proposed listing to assure that each listed color additive will be safe for its intended use or uses in or on food, drugs, or cosmetics. The Commissioner may list a color additive for use generally in or on food, in or on drugs, or in or on cosmetics when he finds from the data presented that such additive is suitable and may safely be employed for such general use; he may list an additive only for more limited use or uses for which it is proven suitable and may safely be employed; and he is authorized to prescribe broadly the conditions under which the additive may be safely employed for such use or uses. This may allow the use of a particular dye, pigment, or other substance with certain diluents, but not with others, or at a higher concentration with some than with others.

(b) The safety for external color additives will normally be determined by tests for acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application. The Commissioner may waive any of such tests if data before him otherwise establish that such test is not required to determine safety for the use proposed.

(c) Upon written request describing the proposed use of a color additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a color additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 70.50 Application of the cancer clause of section 721 of the act.

(a) *Color additives that may be ingested*. Whenever

(1) the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive including its components or impurities has induced cancer when ingested by man or animal; or

(2) tests which are appropriate for the evaluation of the safety of additives in food suggest that the color additive, including its components or impurities, induces cancer in man or animal,

the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, cancer has been induced and whether the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the applicable regulation, it may be listed for such use. But if in the judgment of the Commissioner, based on information from qualified scientists, cancer has been induced, no regulation may issue which permits its use.

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(b) *Color additives that will not be ingested*. Whenever the scientific data before the Commissioner suggest the possibility that the color additive, including its components or impurities, has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the judgment of appropriately qualified scientists, the test suggesting the possibility of carcinogenesis is appropriate for the evaluation of the color additive for a use which does not involve ingestion, cancer has been induced, and the color additive, including its components or impurities, was the causative substance. If it is his judgment that the data do not establish these facts, the cancer clause is not applicable to preclude external drug and cosmetic uses, and if the data as a whole establish that the color additive will be safe under conditions that can be specified in the regulations, it may be listed for such use. But if, in the judgment of the Commissioner, based on information from qualified scientists, the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive, including its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

(c) *Color additives for use as an ingredient of feed for animals that are raised for food production*. Color additives that are an ingredient of the feed for animals raised for food production and that have the potential to contaminate human food with residues whose consumption could present a risk of cancer to people must satisfy the requirements of subpart E of part 500 of this chapter.

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Part 71—Color Additive Petitions

§ 71.1 Petitions.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or cosmetic or for coloring the human body. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. . . .

§ 71.20 Publication of regulation.

The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 721(d)(1) of the act):

(a) A regulation listing in part 73 or 74 of this chapter the color additive on the appropriate list or lists as provided under section 721(b)(1).

(1) Such a regulation may list the color additive for use generally in or on foods, drugs, or cosmetics or for use in coloring the human body, as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such color additive may be used, or for the material intended for coloring the human body; the maximum quantity of any straight color or diluent that may be used or permitted to remain in or on such food, drug, or cosmetic or article intended for coloring the human body; the manner in which such color additive may be added to or used in or on such food, drug, or cosmetic or for coloring the human body; and any directions or other labeling or packing requirements for such color additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(3) The regulation shall list any use or uses in meat, meat food product, or poultry product subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) or the Poultry Products Inspection (PPIA) (21 U.S.C. 451 *et seq.*) for which the color additive has been found suitable and for which it may safely be employed.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

§ 71.37 Exemption of color additives for investigational use.

(a) A shipment or other delivery of a color additive or of a food, drug, or cosmetic containing such a color additive for investigational use by experts qualified to determine safety shall be exempt from the requirements of section 402(c), 501(a), or 601(e) of the act, provided that the color additive or the food, drug, or cosmetic containing the color additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only." No animals used in such investigations, or their products, such as milk or eggs, shall be used for food purposes, unless the sponsor or the investigator has submitted

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to the Commissioner data demonstrating that such use will be consistent with the public health, and the Commissioner, proceeding as he would in a matter involving section 409(i) of the act, has notified the sponsor or investigator that the proposed disposition for food is authorized. Any person who contests a refusal to grant such authorization shall have an opportunity for a regulatory hearing before the Food and Drug Administration pursuant to part 16 of this chapter.

(b) The person who introduced such shipment or who delivers the color additive or a food, drug, or cosmetic containing such an additive into interstate commerce shall maintain adequate records showing the name and post-office address of the expert to whom the color additive is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department, at reasonable times, he shall make such records available for inspection and copying.

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SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

Part 101—Food labeling

§ 101.1. Principal display panel of package form food

The term "principal display panel" as it applies to food in package form and as used in this part, means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The principal display panel shall be large enough to accommodate all the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring design, vignettes, or crowding. . . .

§ 101.2. Information panel of package form food

(a) The term "information panel" as it applies to packaged food means that part of the label immediately contiguous and to the right of the principal display panel as observed by an individual facing the principal display panel . . . .

(b) All information required to appear on the label of any package of food . . . .shall appear either on the principal display panel or on the information panel, unless otherwise specified by regulations in this chapter.

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. . . .

§ 101.3. Identity labeling of food in packaged form

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

(c) Where a food is marketed in various optional forms (whole, slices, diced, etc.), the particular form shall be considered to be a necessary part of the statement of identity and shall be declared in letters of a type size bearing a reasonable relation to the size of the letters forming the other components of the statement of identity . . . .

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

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§ 101.4. Food; designation of ingredients

(a)

(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with § 101.36 need not be repeated in the ingredient list. Paragraph (g) of this section describes the ingredient list on dietary supplement products.

(2) The descending order of predominance requirements of paragraph (a)(1) of this section do not apply to ingredients present in amounts of 2 percent or less by weight when a listing of these ingredients is placed at the end of the ingredient statement following an appropriate quantifying statement, e.g., "Contains ---------- percent or less of ----------," or "Less than ---------- percent of ----------." . . . .

§ 101.9. Nutrition labeling of food

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section.

(1) When food is in package form, the required nutrition labeling information shall appear on the label in the format specified in this section.

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

(3) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling of a food exempted under paragraph (j) of this section to the requirements of this section if the reply to the request conforms to the requirements of this section.

(4) If any vitamin or mineral is added to a food so that a single serving provides 50 percent or more of the Reference Daily Intake (RDI) for the age group for which the product is intended, as specified in paragraph (c)(8)(iv) of this section, of any one of the added vitamins or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this chapter.

(b) Except as provided in § 101.9(h)(3), all nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(1) The term *serving* or *serving size* means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. . . .

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(5) For labeling purposes, the term *common household measure* or *common household unit* means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., ¼ pizza), ounce (oz), fluid ounce (fl oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving size in household measures, except as specified in paragraphs (b)(5)(iv), (b)(5)(v), (b)(5)(vi), and (b)(5)(vii) of this section, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fluid ounces. Cups shall be expressed in ¼ – or ⅓ –cup increments. Tablespoons shall be expressed as 1, 1 ⅓, 1 ½, 1 2/3, 2, or 3 tablespoons. Teaspoons shall be expressed as ⅛, ¼, ½, ¾, 1, or 2 teaspoons.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If paragraphs (b)(5)(i) and (b)(5)(ii) of this section are not applicable, ounces may be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 1 oz (28 g/about ½ pickle). Ounce measurements shall be expressed in 0.5 oz increments most closely approximating the reference amount.

(iv) A description of the individual container or package shall be used for single serving containers and for individually packaged products within multiserving containers (e.g., can, box, package). A description of the individual unit shall be used for other products in discrete units (e.g., piece, slice, cracker, bar).

. . . .

(c) The declaration of nutrition information on the label and in labeling of a food shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (j) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric content per serving, expressed to the nearest 5–calorie increment up to and including 50 calories, and 10–calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content.

. . . .

(ii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5–calorie increment, up to and including 50 calories, and the nearest 10–calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides . . . .

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(3) "Cholesterol": A statement of the cholesterol content in a serving expressed in milligrams to the nearest 5–milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams cholesterol in a serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. Except as provided for in paragraph (f) of this section, if cholesterol content is not required and, as a result, not declared, the statement "Not a significant source of cholesterol" shall be placed at the bottom of the table of nutrient values in the same type size. If the food contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium in a specified serving of food expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5–milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10–milligram increment when the serving contains greater than 140 milligrams.

(5) "Fluoride" (VOLUNTARY): A statement of the number of milligrams of fluoride in a specified serving of food may be declared voluntarily, except that when a claim is made about fluoride content, label declaration shall be required. Fluoride content shall be expressed as zero when the serving contains less than 0.1 milligrams of fluoride, to the nearest 0.1–milligram increment when the serving contains less than or equal to 0.8 milligrams of fluoride, and the nearest 0.2 milligram-increment when a serving contains more than 0.8 milligrams of fluoride. Bottled water that bears a statement about added fluoride, as permitted by § 101.13(q)(8), must bear nutrition labeling that complies with requirements for the simplified format in paragraph (f) of this section.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate in a serving expressed to the nearest gram . . . .

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram . . . .

(8) "Vitamins and minerals": The requirements related to including a statement of the amount per serving of vitamins and minerals are described in this paragraph (c)(8).

. . . .

§ 101.13. Nutrient content claims—general principles

(a) This section and the regulations in subpart D of this part apply to foods that are intended for human consumption and that are offered for sale, including conventional foods and dietary supplements.

(b) A claim that expressly or implicitly characterizes the level of a nutrient of the type required to be in nutrition labeling under §101.9 or under §101.36 (that is, a nutrient content claim) may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

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(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

. . . .

§ 101.14. Health claims: general requirements

(a) *Definitions*. For purposes of this section, the following definitions apply:

(1) *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) *Substance* means a specific food or component of food, regardless of whether the food is in conventional food form or a dietary supplement that includes vitamins, minerals, herbs, or other similar nutritional substances.

(3) *Nutritive value* means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in §101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in §101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(5) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to §101.14 or §101.70).

(b) *Eligibility*. For a substance to be eligible for a health claim:

(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease

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or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q)(1)(C) or (q)(1)(D), or one that the Food and Drug Administration (FDA) has required to be included in the label or labeling under 21 U.S.C. 343(q)(2)(A); or

(3) If the substance is to be consumed at other than decreased dietary levels:

(i) The substance must, regardless of whether the food is a conventional food or a dietary supplement, contribute taste, aroma, or nutritive value, or any other technical effect listed in §170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act.

(c) *Validity requirement.* FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(d) *General health claim labeling requirements.*

(1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of this section, FDA will propose a regulation in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in §101.9 or §101.36, FDA will propose amending that regulation to include declaration of the substance.

(2) When FDA has adopted a regulation in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statements about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the regulations in subpart E of this part;

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the label or labeling may bear the reference statement, "See ___ for information about the relationship between ___ and ___," with the blanks filled in with the location of the labeling containing the health claim, the name of the

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substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other labeling, Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term low has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term high for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established (e.g., where the claim pertains to a food either as a whole food or as an ingredient in another food), the claim must specify the daily dietary intake necessary to achieve the claimed effect, as established in the regulation authorizing the claim; *Provided* That:

(A) Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors. A serving of _ ounces of this product conforms to such a diet.").

(B) Where the food that bears the claim is sold in a restaurant or in other establishments in which food that is ready for immediate human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section and provides that basis upon request.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with §101.9; for restaurant foods, in accordance with §101.10; or for dietary supplements, in accordance with §101.36.

(e) *Prohibited health claims.* No expressed or implied health claim may be made on the label or in labeling for a food, regardless of whether the food is in conventional food form or dietary supplement form, unless:

(1) The claim is specifically provided for in subpart E of this part; and

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(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(4) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a disqualifying level of a nutrient is present in the food based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E of this part that makes such a finding, the label bears a disclosure statement that complies with §101.13(h), highlighting the nutrient that exceeds the disqualifying level;

(4) Except as provided in paragraph (e)(3) of this section, no substance is present at an inappropriate level as determined in the specific provision authorizing the claim in subpart E of this part;

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age except if the claim is specifically provided for in subpart E of this part; and

(6) Except for dietary supplements or where provided for in other regulations in part 101, subpart E, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act.

(g) *Applicability*. The requirements of this section apply to foods intended for human consumption that are offered for sale, regardless of whether the foods are in conventional food form or dietary supplement form.

§ 101.15. Food; prominence of required statements

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

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(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

. . . .

§ 101.18. Misbranding of food

(a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(c) Among representations in the labeling of a food which render such food misbranded is any representation that expresses or implies a geographical origin of the food or any ingredient of the food except when such representation is either:

(1) A truthful representation of geographical origin.

(2) A trademark or trade name provided that as applied to the article in question its use is not deceptively misdescriptive. A trademark or trade name composed in whole or in part of geographical words shall not be considered deceptively misdescriptive if it:

(i) Has been so long and exclusively used by a manufacturer or distributor that it is generally understood by the consumer to mean the product of a particular manufacturer or distributor; or

(ii) Is so arbitrary or fanciful that it is not generally understood by the consumer to suggest geographic origin.

(3) A part of the name required by applicable Federal law or regulation.

(4) A name whose market significance is generally understood by the consumer to connote a particular class, kind, type, or style of food rather than to indicate geographical origin.

§ 101.93. Certain types of statements for dietary supplements

(a)

(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Dietary Supplement Programs (HFS–810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

(ii) The text of the statement that is being made;

(iii) The name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement; and

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(iv) The name of the dietary supplement (including brand name), if not provided in response to paragraph (a)(2)(iii) on whose label, or in whose labeling, the statement appears.

(3) The notice shall be signed by a responsible individual or the person who can certify the accuracy of the information presented and contained in the notice. The individual shall certify that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

(b) *Disclaimer*. The requirements in this section apply to the label or labeling of dietary supplements where the dietary supplement bears a statement that is provided for by section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), and the manufacturer, packer, or distributor wishes to take advantage of the exemption to section 201(g)(1)(C) of the act that is provided by compliance with section 403(r)(6) of the act.

(c) *Text for disclaimer*.

(1) Where there is one statement, the disclaimer shall be placed in accordance with paragraph (d) of this section and shall state:

> This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(2) Where there is more than one such statement on the label or in the labeling, each statement shall bear the disclaimer in accordance with paragraph (c)(1) of this section, or a plural disclaimer may be placed in accordance with paragraph (d) of this section and shall state:

> These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

(d) *Placement*. The disclaimer shall be placed adjacent to the statement with no intervening material or linked to the statement with a symbol (e.g., an asterisk) at the end of each such statement that refers to the same symbol placed adjacent to the disclaimer specified in paragraphs (c)(1) or (c)(2) of this section. On product labels and in labeling (e.g., pamphlets, catalogs), the disclaimer shall appear on each panel or page where there such is a statement. The disclaimer shall be set off in a box where it is not adjacent to the statement in question.

(e) *Typesize*. The disclaimer in paragraph (c) of this section shall appear in boldface type in letters of a typesize no smaller than one-sixteenth inch.

(f) *Permitted structure/function statements*. Dietary supplement labels or labeling may, subject to the requirements in paragraphs (a) through (e) of this section, bear statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, provided that such statements are not disease claims under paragraph (g) of this section. If the label or labeling of a product marketed as a dietary supplement bears a disease claim as defined in paragraph (g) of this section, the product will be subject to regulation as a drug unless the claim is an authorized health claim for which the product qualifies.

(g) *Disease claims*.

(1) For purposes of 21 U.S.C. 343(r)(6), a "disease" is damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition.

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(2) FDA will find that a statement about a product claims to diagnose, mitigate, treat, cure, or prevent disease (other than a classical nutrient deficiency disease) under 21 U.S.C. 343(r)(6) if it meets one or more of the criteria listed below. These criteria are not intended to classify as disease claims statements that refer to the ability of a product to maintain healthy structure or function, unless the statement implies disease prevention or treatment. In determining whether a statement is a disease claim under these criteria, FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product:

(i) Has an effect on a specific disease or class of diseases;

(ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology;

(iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm;

(iv) Has an effect on a disease or diseases through one or more of the following factors:

(A) The name of the product;

(B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of "dietary supplement" under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease;

(C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product's express claims;

(D) Use of the term "disease" or "diseased," except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or

(E) Use of pictures, vignettes, symbols, or other means;

(v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease;

(vi) Is a substitute for a product that is a therapy for a disease;

(vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases;

(viii) Has a role in the body's response to a disease or to a vector of disease;

(ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or

(x) Otherwise suggests an effect on a disease or diseases.

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Part 102—Common or usual name for nonstandardized foods

§ 102.5. General principles

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modfied by a specific regulation in subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) _ percent (or %) ___" or "_ percent (or %) ___" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "_ percent or %) ___" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s)

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or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___" or "containing (or contains) no ___" or "no ___" or "does not contain ___", with the blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c)(1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraphs (b)(2)(i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in subpart B of this part, in part 104 of this chapter, in a standard of identity, or in other regulations in this chapter.

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Part 105—Foods for special dietary use

§ 105.3. Definitions and interpretations

The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act (hereafter "the act") shall be applicable with the following additions:

(a)

(1) The term *special dietary uses*, as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(i) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of diseases, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(ii) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(iii) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(2) The use of an artificial sweetener in a food, except when specifically and solely used for achieving a physical characteristic in the food which cannot be achieved with sugar or other nutritive sweetener, shall be considered a use for regulation of the intake of calories and available carbohydrate, or for use in the diets of diabetics and is therefore a special dietary use.

. . . .

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Part 117—Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food

§ 117.1. Applicability and Status [of 21 C.F.R. Part 117 more generally]

[Note: this section sets out the applicability of 21 C.F.R. Part 117—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food]

(a) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been manufactured under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; and

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

(b) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is required to comply with, and is not in compliance with, section 418 of the Federal Food, Drug, and Cosmetic Act or subpart C, D, E, F, or G of this part is a prohibited act under section 301(uu) of the Federal Food, Drug, and Cosmetic Act.

(c) Food covered by specific current good manufacturing practice regulations also is subject to the requirements of those regulations.

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Part 190—Dietary supplements

§ 190.6. Requirement for premarket notification

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered, the manufacturer or distributor of that supplement, or of the new dietary ingredient, shall submit to the Office of Dietary Supplement Programs (HFS–810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, information including any citation to published articles that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. An original and two copies of this notification shall be submitted.

(b) The notification required by paragraph (a) of this section shall include:

(1) The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;

(2) The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

(4) The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient

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notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

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SUBCHAPTER D—DRUGS FOR HUMAN USE

Part 310—New drugs

§ 310.6. Applicability of "new drug" or safety or effectiveness findings in drug efficacy study implementation notices and notices of opportunity for hearing to identical, related, and similar drug products

(a) The Food and Drug Administration's conclusions on the effectiveness of drugs are currently being published in the FEDERAL REGISTER as Drug Efficacy Study Implementation (DESI) Notices and as Notices of Opportunity for Hearing. The specific products listed in these notices include only those that were introduced into the market through the new drug procedures from 1938-62 and were submitted for review by the National Academy of Sciences-National Research Council (NAS-NRC), Drug Efficacy Study Group. Many products which are identical to, related to, or similar to the products listed in these notices have been marketed under different names or by different firms during this same period or since 1962 without going through the new drug procedures or the Academy review. Even though these products are not listed in the notices, they are covered by the new drug applications reviewed and thus are subject to these notices. All persons with an interest in a product that is identical, related, or similar to a drug listed in a drug efficacy notice or a notice of opportunity for a hearing will be given the same opportunity as the applicant to submit data and information, to request a hearing, and to participate in any hearing. It is not feasible for the Food and Drug Administration to list all products which are covered by an NDA and thus subject to each notice. However, it is essential that the findings and conclusions that a drug product is a "new drug" or that there is a lack of evidence to show that a drug product is safe or effective be applied to all identical, related, and similar drug products to which they are reasonably applicable. Any product not in compliance with an applicable drug efficacy notice is in violation of section 505 (new drugs) and/or section 502 (misbranding) of the act.

. . . .

(f) This regulation does not apply to OTC drugs identical, similar, or related to a drug in the Drug Efficacy Study unless there has been or is notification in the FEDERAL REGISTER that a drug will not be subject to an OTC panel review pursuant to §§330.10, 330.11, and 330.5 of this chapter.

§310.100. New drug status opinions; statement of policy

(a) Over the years since 1938 the Food and Drug Administration has given informal advice to inquirers as to the new drug status of preparations. These drugs have sometimes been identified only by general statements of composition. Generally, such informal opinions were incorporated in letters that did not explicitly relate all of the necessary conditions and qualifications such as the quantitative formula for the drug and the conditions under which it was prescribed, recommended, or suggested. This has contributed to misunderstanding and misinterpretation of such opinions.

(b) These informal opinions that an article is "not a new drug" or "no longer a new drug" require reexamination under the Kefauver-Harris Act (Public Law 87-781; 76 Stat. 788-89). In particular, when approval of a new drug application is withdrawn under provisions of section 505(e) of the Federal Food, Drug, and Cosmetic Act, a drug generally recognized as safe may become a "new drug" within the meaning of section 201(p) of said act as amended by the Kefauver-Harris Act on October 10, 1962. This is of special importance by reason of proposed actions to withdraw approval of new drug applications for

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lack of substantial evidence of effectiveness as a result of reports of the National Academy of Sciences—National Research Council on its review of drug effectiveness; for example, see the notice published in the FEDERAL REGISTER of January 23, 1968 (33 FR 818), regarding rutin, quercetin, et al.

(c) Any marketed drug is a "new drug" if any labeling change made after October 9, 1962, recommends or suggests new conditions of use under which the drug is not generally recognized as safe and effective by qualified experts. Undisclosed or unreported side effects as well as the emergence of new knowledge presenting questions with respect to the safety or effectiveness of a drug may result in its becoming a "new drug" even though it was previously considered "not a new drug." Any previously given informal advice that an article is "not a new drug" does not apply to such an article if it has been changed in formulation, manufacture control, or labeling in a way that may significantly affect the safety of the drug.

(d) For these reasons, all opinions previously given by the Food and Drug Administration to the effect that an article is "not a new drug" or is "no longer a new drug" are hereby revoked. This does not mean that all articles that were the subjects of such prior opinions will be regarded as new drugs. The prior opinions will be replaced by opinions of the Food and Drug Administration that are qualified and current on when an article is "not a new drug," as set forth in this subchapter.

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Part 314— Applications for FDA approval to market a new drug

§ 314.70. Supplements and other changes to an approved NDA

(a) *Changes to an approved NDA.*

(1)

(i) Except as provided in paragraph (a)(1)(ii) of this section, the applicant must notify FDA about each change in each condition established in an approved NDA beyond the variations already provided for in the NDA. The notice is required to describe the change fully. Depending on the type of change, the applicant must notify FDA about the change in a supplement under paragraph (b) or (c) of this section or by inclusion of the information in the annual report to the NDA under paragraph (d) of this section.

(ii) The submission and grant of a written request for an exception or alternative under § 201.26 of this chapter satisfies the applicable requirements in paragraphs (a) through (c) of this section. However, any grant of a request for an exception or alternative under § 201.26 of this chapter must be reported as part of the annual report to the NDA under paragraph (d) of this section.

. . . .

(b) *Changes requiring supplement submission and approval prior to distribution of the product made using the change (major changes).*

(1) A supplement must be submitted for any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

(2) These changes include, but are not limited to:

. . . .

(v) The following labeling changes:

(A) Changes in labeling, except those described in paragraphs (c)(6)(iii), (d)(2)(ix), or (d)(2)(x) of this section;

(B) If applicable, any change to a Medication Guide required under part 208 of this chapter, except for changes in the information specified in § 208.20(b)(8)(iii) and (b)(8)(iv) of this chapter; and

(C) Any change to the information required by § 201.57(a) of this chapter, with the following exceptions that may be reported in an annual report under paragraph (d)(2)(x) of this section:

(1) Removal of a listed section(s) specified in § 201.57(a)(5) of this chapter; and

(2) Changes to the most recent revision date of the labeling as specified in § 201.57(a)(15) of this chapter.

. . . .

(3) The applicant must obtain approval of a supplement from FDA prior to distribution of a drug product made using a change under paragraph (b) of this section. . . .

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(c) *Changes requiring supplement submission at least 30 days prior to distribution of the drug product made using the change (moderate changes).*

. . . .

(6) The agency may designate a category of changes for the purpose of providing that, in the case of a change in such category, the holder of an approved NDA may commence distribution of the drug product involved upon receipt by the agency of a supplement for the change. These changes include, but are not limited to:

. . . .

(iii) Changes in the labeling to reflect newly acquired information, except for changes to the information required in § 201.57(a) of this chapter (which must be made under paragraph (b)(2)(v)(C) of this section), to accomplish any of the following:

(A) To add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter;

(B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;

(C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;

(D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or

(E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

(7) If the agency disapproves the supplemental NDA, it may order the manufacturer to cease distribution of the drug product(s) made with the manufacturing change.

(d) *Changes to be described in an annual report (minor changes).*

. . . .

§314.125. Refusal to approve an NDA

. . . .

(b) FDA may refuse to approve an NDA for any of the following reasons, unless the requirement has been waived under §314.90:

. . . .

(2) The investigations required under section 505(b) of the Federal Food, Drug, and Cosmetic Act do not include adequate tests by all methods reasonably applicable to show whether or not the drug is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(3) The results of the tests show that the drug is unsafe for use under the conditions prescribed, recommended, or suggested in its proposed labeling or the results do not show that the drug product is safe for use under those conditions.

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(4) There is insufficient information about the drug to determine whether the product is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling.

(5) There is a lack of substantial evidence consisting of adequate and well-controlled investigations, as defined in §314.126, that the drug product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling.

(6) The proposed labeling is false or misleading in any particular.

. . . .

§314.126. Adequate and well-controlled studies

(a) The purpose of conducting clinical investigations of a drug is to distinguish the effect of a drug from other influences, such as spontaneous change in the course of the disease, placebo effect, or biased observation. The characteristics described in paragraph (b) of this section have been developed over a period of years and are recognized by the scientific community as the essentials of an adequate and well-controlled clinical investigation. The Food and Drug Administration considers these characteristics in determining whether an investigation is adequate and well-controlled for purposes of section 505 of the act. Reports of adequate and well-controlled investigations provide the primary basis for determining whether there is "substantial evidence" to support the claims of effectiveness for new drugs. Therefore, the study report should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

(b) An adequate and well-controlled study has the following characteristics:

(1) There is a clear statement of the objectives of the investigation and a summary of the proposed or actual methods of analysis in the protocol for the study and in the report of its results. In addition, the protocol should contain a description of the proposed methods of analysis, and the study report should contain a description of the methods of analysis ultimately used. If the protocol does not contain a description of the proposed methods of analysis, the study report should describe how the methods used were selected.

(2) The study uses a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect. The protocol for the study and report of results should describe the study design precisely; for example, duration of treatment periods, whether treatments are parallel, sequential, or crossover, and whether the sample size is predetermined or based upon some interim analysis. Generally, the following types of control are recognized:

(i) *Placebo concurrent control*. The test drug is compared with an inactive preparation designed to resemble the test drug as far as possible. A placebo-controlled study may include additional treatment groups, such as an active treatment control or a dose-comparison control, and usually includes randomization and blinding of patients or investigators, or both.

(ii) *Dose-comparison concurrent control*. At least two doses of the drug are compared. A dose-comparison study may include additional treatment groups, such as placebo control or active control. Dose-comparison trials usually include randomization and blinding of patients or investigators, or both.

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(iii) *No treatment concurrent control*. Where objective measurements of effectiveness are available and placebo effect is negligible, the test drug is compared with no treatment. No treatment concurrent control trials usually include randomization.

(iv) *Active treatment concurrent control*. The test drug is compared with known effective therapy; for example, where the condition treated is such that administration of placebo or no treatment would be contrary to the interest of the patient. An active treatment study may include additional treatment groups, however, such as a placebo control or a dose-comparison control. Active treatment trials usually include randomization and blinding of patients or investigators, or both. If the intent of the trial is to show similarity of the test and control drugs, the report of the study should assess the ability of the study to have detected a difference between treatments. Similarity of test drug and active control can mean either that both drugs were effective or that neither was effective. The analysis of the study should explain why the drugs should be considered effective in the study, for example, by reference to results in previous placebo-controlled studies of the active control drug.

(v) *Historical control*. The results of treatment with the test drug are compared with experience historically derived from the adequately documented natural history of the disease or condition, or from the results of active treatment, in comparable patients or populations. Because historical control populations usually cannot be as well assessed with respect to pertinent variables as can concurrent control populations, historical control designs are usually reserved for special circumstances. Examples include studies of diseases with high and predictable mortality (for example, certain malignancies) and studies in which the effect of the drug is self-evident (general anesthetics, drug metabolism).

(3) The method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed.

(4) The method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables such as age, sex, severity of disease, duration of disease, and use of drugs or therapy other than the test drug. The protocol for the study and the report of its results should describe how subjects were assigned to groups. Ordinarily, in a concurrently controlled study, assignment is by randomization, with or without stratification.

(5) Adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data. The protocol and report of the study should describe the procedures used to accomplish this, such as blinding.

(6) The methods of assessment of subjects' response are well-defined and reliable. The protocol for the study and the report of results should explain the variables measured, the methods of observation, and criteria used to assess response.

(7) There is an analysis of the results of the study adequate to assess the effects of the drug. The report of the study should describe the results and the analytic methods used to evaluate them, including any appropriate statistical methods. The analysis should assess, among other things, the comparability of test and control groups with respect to pertinent variables, and the effects of any interim data analyses performed.

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(c) The Director of the Center for Drug Evaluation and Research may, on the Director's own initiative or on the petition of an interested person, waive in whole or in part any of the criteria in paragraph (b) of this section with respect to a specific clinical investigation, either prior to the investigation or in the evaluation of a completed study. . . .

(d) For an investigation to be considered adequate for approval of a new drug, it is required that the test drug be standardized as to identity, strength, quality, purity, and dosage form to give significance to the results of the investigation.

(e) Uncontrolled studies or partially controlled studies are not acceptable as the sole basis for the approval of claims of effectiveness. Such studies carefully conducted and documented, may provide corroborative support of well-controlled studies regarding efficacy and may yield valuable data regarding safety of the test drug. Such studies will be considered on their merits in the light of the principles listed here, with the exception of the requirement for the comparison of the treated subjects with controls. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

§ 314.600. Scope

This subpart applies to certain new drug products that have been studied for their safety and efficacy in ameliorating or preventing serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substances. This subpart applies only to those new drug products for which: Definitive human efficacy studies cannot be conducted because it would be unethical to deliberately expose healthy human volunteers to a lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substance; and field trials to study the product's effectiveness after an accidental or hostile exposure have not been feasible. This subpart does not apply to products that can be approved based on efficacy standards described elsewhere in FDA's regulations (e.g., accelerated approval based on surrogate markers or clinical endpoints other than survival or irreversible morbidity), nor does it address the safety evaluation for the products to which it does apply.

§ 314.610. Approval based on evidence of effectiveness from studies in animals

(a) FDA may grant marketing approval for a new drug product for which safety has been established and for which the requirements of § 314.600 are met based on adequate and well-controlled animal studies when the results of those animal studies establish that the drug product is reasonably likely to produce clinical benefit in humans. In assessing the sufficiency of animal data, the agency may take into account other data, including human data, available to the agency. FDA will rely on the evidence from studies in animals to provide substantial evidence of the effectiveness of these products only when:

(1) There is a reasonably well-understood pathophysiological mechanism of the toxicity of the substance and its prevention or substantial reduction by the product;

(2) The effect is demonstrated in more than one animal species expected to react with a response predictive for humans, unless the effect is demonstrated in a single animal species that represents a sufficiently well-characterized animal model for predicting the response in humans;

(3) The animal study endpoint is clearly related to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity; and

(4) The data or information on the kinetics and pharmacodynamics of the product or other relevant data or information, in animals and humans, allows selection of an effective dose in humans.

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(b) Approval under this subpart will be subject to three requirements:

(1) *Postmarketing studies*. The applicant must conduct postmarketing studies, such as field studies, to verify and describe the drug's clinical benefit and to assess its safety when used as indicated when such studies are feasible and ethical. Such postmarketing studies would not be feasible until an exigency arises. When such studies are feasible, the applicant must conduct such studies with due diligence. Applicants must include as part of their application a plan or approach to postmarketing study commitments in the event such studies become ethical and feasible.

(2) *Approval with restrictions to ensure safe use*. If FDA concludes that a drug product shown to be effective under this subpart can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to ensure safe use of the drug product, commensurate with the specific safety concerns presented by the drug product, such as:

(i) Distribution restricted to certain facilities or health care practitioners with special training or experience;

(ii) Distribution conditioned on the performance of specified medical procedures, including medical followup; and

(iii) Distribution conditioned on specified recordkeeping requirements.

(3) *Information to be provided to patient recipients*. For drug products or specific indications approved under this subpart, applicants must prepare, as part of their proposed labeling, labeling to be provided to patient recipients. The patient labeling must explain that, for ethical or feasibility reasons, the drug's approval was based on efficacy studies conducted in animals alone and must give the drug's indication(s), directions for use (dosage and administration), contraindications, a description of any reasonably foreseeable risks, adverse reactions, anticipated benefits, drug interactions, and any other relevant information required by FDA at the time of approval. The patient labeling must be available with the product to be provided to patients prior to administration or dispensing of the drug product for the use approved under this subpart, if possible.

§ 314.640. Promotional materials

For drug products being considered for approval under this subpart, unless otherwise informed by the agency, applicants must submit to the agency for consideration during the preapproval review period copies of all promotional materials, including promotional labeling as well as advertisements, intended for dissemination or publication within 120 days following marketing approval. After 120 days following marketing approval, unless otherwise informed by the agency, the applicant must submit promotional materials at least 30 days prior to the intended time of initial dissemination of the labeling or initial publication of the advertisement.

§ 314.650. Termination of requirements

If FDA determines after approval under this subpart that the requirements established in [various other portions of this subpart] are no longer necessary for the safe and effective use of a drug product, FDA will so notify the applicant. Ordinarily, for drug products approved under § 314.610, these requirements will no longer apply when FDA determines that the postmarketing study verifies and describes the drug product's clinical benefit. For drug products approved under § 314.610, the restrictions would no longer apply when FDA determines that safe use of the drug product can be ensured through appropriate labeling.

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FDA also retains the discretion to remove specific postapproval requirements upon review of a petition submitted by the sponsor . . . .

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SUBCHAPTER E—Animal Drugs, Feeds, and Related Products

Part 510—New animal drugs

§ 510.3. Definitions and interpretations

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(g) The term *new animal drug* means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed:

(1) The composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; except that such a drug not so recognized shall not be deemed to be a *new animal drug* if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) The composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

. . . .

(i) The newness of an animal drug, including a new animal drug intended for use in or on animal feed, may arise by reason of:

(1) The newness for its intended drug use of any substance of which the drug is comprised, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component;

(2) the newness for its intended drug use of a combination of two or more substances, none of which is itself a new animal drug;

(3) the newness for its intended drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new animal drug;

(4) the newness for its intended drug use in a different species of animal;

(5) the newness of its intended drug use in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the animal body, even though such drug is not a new animal drug when used in another disease or to affect another structure or function of the body; or

(6) the newness of a dosage, or method or duration of administration or application, or any other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug or animal feed containing such drug when used in another dosage, or another method or duration of administration or application, or different condition, is not a new animal drug.

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§ 510.4. Biologics; products subject to license control

An animal drug produced and distributed in full conformance with the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 *et seq*.) and any regulations issued thereunder shall not be deemed to be subject to section 512 of the Federal Food, Drug, and Cosmetic Act.

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Part 514—New animal drug applications

§ 514.4. Substantial evidence

(a) *Definition of substantial evidence*. Substantial evidence means evidence consisting of one or more adequate and well-controlled studies, such as a study in a target species, study in laboratory animals, field study, bioequivalence study, or an in vitro study, on the basis of which it could fairly and reasonably be concluded by experts qualified by scientific training and experience to evaluate the effectiveness of the new animal drug involved that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. Substantial evidence shall include such adequate and well-controlled studies that are, as a matter of sound scientific judgment, necessary to establish that a new animal drug will have its intended effect.

. . . .

§514.111. Refusal to approve an application

(a) The Commissioner shall, within 180 days after the filing of the application, inform the applicant in writing of his intention to issue a notice of opportunity for a hearing on a proposal to refuse to approve the application, if the Commissioner determines upon the basis of the application, or upon the basis of other information before him with respect to a new animal drug, that:

(1) The reports of investigations required to be submitted pursuant to section 512(b) of the act do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or

(2) The results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; or

(3) The methods used in and the facilities and controls used for the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or

(4) Upon the basis of the information submitted to the Food and Drug Administration as part of the application, or upon the basis of any other information before it with respect to such drug, it has insufficient information to determine whether such drug is safe for use under such conditions. In making this determination the Commissioner shall consider, among other relevant factors:

(i) The probable consumption of such drug and of any substance formed in or on food because of the use of such drug;

(ii) The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substances;

(iii) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data; and

(iv) Whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice; or

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence as defined in §514.4.

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(6) Failure to include an appropriate proposed tolerance for residues in edible products derived from animals or a withdrawal period or other restrictions for use of such drug if any tolerance or withdrawal period or other restrictions for use are required in order to assure that the edible products derived from animals treated with such drug will be safe.

(7) Based on a fair evaluation of all material facts, the labeling is false or misleading in any particular, or

. . . .

§ 514.117. Adequate and well-controlled studies

(a) *Purpose*. The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well controlled, as used in the phrase adequate and well controlled, emphasizes an important aspect of adequacy. The Food and Drug Administration (FDA) considers these characteristics in determining whether a study is adequate and well controlled for purposes of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b). Adequate and well-controlled studies, in addition to providing a basis for determining whether a new animal drug is effective, may also be relied upon to support target animal safety. The report of an adequate and well-controlled study should provide sufficient details of study design, conduct, and analysis to allow critical evaluation and a determination of whether the characteristics of an adequate and well-controlled study are present.

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Part 530—Extralabel drug use in animals

§530.1. Scope

This part applies to the extralabel use in an animal of any approved new animal drug or approved new human drug by or on the lawful order of a licensed veterinarian within the context of a valid veterinary-client-patient relationship.

§530.2. Purpose

The purpose of this part is to establish conditions for extralabel use or intended extralabel use in animals by or on the lawful order of licensed veterinarians of Food and Drug Administration approved new animal drugs and approved new human drugs. Such use is limited to treatment modalities when the health of an animal is threatened or suffering or death may result from failure to treat. This section implements the Animal Medicinal Drug Use Clarification Act of 1994 (the AMDUCA) (Pub. L. 103-396).

§530.3. Definitions

(a) *Extralabel use* means actual use or intended use of a drug in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

. . . .

(f) A *residue* means any compound present in edible tissues that results from the use of a drug, and includes the drug, its metabolites, and any other substance formed in or on food because of the drug's use.

(g) A *safe level* is a conservative estimate of a drug residue level in edible animal tissue derived from food safety data or other scientific information. Concentrations of residues in tissue below the safe level will not raise human food safety concerns. A safe level is not a safe concentration or a tolerance and does not indicate that an approval exists for the drug in that species or category of animal from which the food is derived.

. . . .

(i) A *valid veterinarian-client-patient relationship* is one in which:

(1) A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian;

(2) There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and

(3) The practicing veterinarian is readily available for followup in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

§530.4. Advertising and promotion

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Nothing in this part shall be construed as permitting the advertising or promotion of extralabel uses in animals of approved new animal drugs or approved human drugs.

§530.5. Veterinary records

(a) As a condition of extralabel use permitted under this part, to permit FDA to ascertain any extralabel use or intended extralabel use of drugs that the agency has determined may present a risk to the public health, veterinarians shall maintain the following records of extralabel uses. Such records shall be legible, documented in an accurate and timely manner, and be readily accessible to permit prompt retrieval of information. Such records shall be adequate to substantiate the identification of the animals and shall be maintained either as individual records or, in food animal practices, on a group, herd, flock, or per-client basis. . . .

§530.10. Provision permitting extralabel use of animal drugs

An approved new animal drug or human drug intended to be used for an extralabel purpose in an animal is not unsafe under section 512 of the act and is exempt from the labeling requirements of section 502(f) of the act if such use is:

(a) By or on the lawful written or oral order of a licensed veterinarian within the context of a valid veterinarian-client-patient relationship; and

(b) In compliance with this part.

§530.11. Limitations

In addition to uses which do not comply with the provision set forth in §530.10, the following specific extralabel uses are not permitted and result in the drug being deemed unsafe within the meaning of section 512 of the act:

(a) Extralabel use in an animal of an approved new animal drug or human drug by a lay person (except when under the supervision of a licensed veterinarian);

(b) Extralabel use of an approved new animal drug or human drug in or on an animal feed;

(c) Extralabel use resulting in any residue which may present a risk to the public health; and

(d) Extralabel use resulting in any residue above an established safe level, safe concentration or tolerance.

§530.20. Conditions for permitted extralabel animal and human drug use in food-producing animals

(a) The following conditions must be met for a permitted extralabel use in food-producing animals of approved new animal and human drugs:

(1) There is no approved new animal drug that is labeled for such use and that contains the same active ingredient which is in the required dosage form and concentration, except where a veterinarian finds, within the context of a valid veterinarian-client-patient relationship, that the approved new animal drug is clinically ineffective for its intended use.

(2) Prior to prescribing or dispensing an approved new animal or human drug for an extralabel use in food animals, the veterinarian must:

(i) Make a careful diagnosis and evaluation of the conditions for which the drug is to be used;

(ii) Establish a substantially extended withdrawal period prior to marketing of milk, meat, eggs, or other edible products supported by appropriate scientific information, if applicable;

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(iii) Institute procedures to assure that the identity of the treated animal or animals is carefully maintained; and

(iv) Take appropriate measures to assure that assigned timeframes for withdrawal are met and no illegal drug residues occur in any food-producing animal subjected to extralabel treatment.

(b) The following additional conditions must be met for a permitted extralabel use of in food-producing animals an approved human drug, or of an animal drug approved only for use in animals not intended for human consumption:

(1) Such use must be accomplished in accordance with an appropriate medical rationale; and

(2) If scientific information on the human food safety aspect of the use of the drug in food-producing animals is not available, the veterinarian must take appropriate measures to assure that the animal and its food products will not enter the human food supply.

(c) Extralabel use of an approved human drug in a food-producing animal is not permitted under this part if an animal drug approved for use in food-producing animals can be used in an extralabel manner for the particular use.

§530.21. Prohibitions for food-producing animals

(a) FDA may prohibit the extralabel use of an approved new animal or human drug or class of drugs in food-producing animals if FDA determines that:

(1) An acceptable analytical method needs to be established and such method has not been established or cannot be established; or

(2) The extralabel use of the drug or class of drugs presents a risk to the public health.

(b) A prohibition may be a general ban on the extralabel use of the drug or class of drugs or may be limited to a specific species, indication, dosage form, route of administration, or combination of factors.

§530.30. Extralabel drug use in nonfood animals

(a) Because extralabel use of animal and human drugs in nonfood-producing animals does not ordinarily pose a threat to the public health, extralabel use of animal and human drugs is permitted in nonfood-producing animal practice except when the public health is threatened. In addition, the provisions of §530.20(a)(1) will apply to the use of an approved animal drug.

(b) If FDA determines that an extralabel drug use in animals not intended for human consumption presents a risk to the public health, the agency may publish in the FEDERAL REGISTER a notice prohibiting such use following the procedures in §530.25. The prohibited extralabel drug use will be codified in §530.41.

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SUBCHAPTER F—BIOLOGICS

Part 600 - General

§ 600.3 Definitions.

As used in this subchapter:

. . . .

(h) *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(1) A virus is interpreted to be a product containing the minute living cause of an infectious disease and includes but is not limited to filterable viruses, bacteria, rickettsia, fungi, and protozoa.

(2) A therapeutic serum is a product obtained from blood by removing the clot or clot components and the blood cells.

(3) A toxin is a product containing a soluble substance poisonous to laboratory animals or to man in doses of 1 milliliter or less (or equivalent in weight) of the product, and having the property, following the injection of non-fatal doses into an animal, of causing to be produced therein another soluble substance which specifically neutralizes the poisonous substance and which is demonstrable in the serum of the animal thus immunized.

(4) An antitoxin is a product containing the soluble substance in serum or other body fluid of an immunized animal which specifically neutralizes the toxin against which the animal is immune.

(5) A product is analogous:

(i) To a virus if prepared from or with a virus or agent actually or potentially infectious, without regard to the degree of virulence or toxicogenicity of the specific strain used.

(ii) To a therapeutic serum, if composed of whole blood or plasma or containing some organic constituent or product other than a hormone or an amino acid, derived from whole blood, plasma, or serum.

(iii) To a toxin or antitoxin, if intended, irrespective of its source of origin, to be applicable to the prevention, treatment, or cure of disease or injuries of man through a specific immune process.

(6) A protein is any alpha amino acid polymer with a specific, defined sequence that is greater than 40 amino acids in size. When two or more amino acid chains in an amino acid polymer are associated with each other in a manner that occurs in nature, the size of the amino acid polymer for purposes of this paragraph (h)(6) will be based on the total number of amino acids in those chains, and will not be limited to the number of amino acids in a contiguous sequence.

(i) *Trivalent organic arsenicals* means arsphenamine and its derivatives (or any other trivalent organic arsenic compound) applicable to the prevention, treatment, or cure of diseases or injuries of man.

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(j) A product is deemed *applicable to the prevention, treatment, or cure of diseases or injuries of man* irrespective of the mode of administration or application recommended, including use when intended through administration or application to a person as an aid in diagnosis, or in evaluating the degree of susceptibility or immunity possessed by a person, and including also any other use for purposes of diagnosis if the diagnostic substance so used is prepared from or with the aid of a biological product.

. . . .

(p) The word *safety* means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time.

(q) The word *sterility* is interpreted to mean freedom from viable contaminating microorganisms, as determined by the tests conducted under §610.12 of this chapter.

(r) *Purity* means relative freedom from extraneous matter in the finished product, whether or not harmful to the recipient or deleterious to the product. Purity includes but is not limited to relative freedom from residual moisture or other volatile substances and pyrogenic substances.

(s) The word *potency* is interpreted to mean the specific ability or capacity of the product, as indicated by appropriate laboratory tests or by adequately controlled clinical data obtained through the administration of the product in the manner intended, to effect a given result.

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Part 601—Licensing

§ 601.2. Applications for biologics licenses; procedures for filing

(a) *General*. To obtain a biologics license under section 351 of the Public Health Service Act for any biological product, the manufacturer shall submit an application to the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research . . . .

(d) Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products. Applicable requirements for the maintenance of establishments for the manufacture of a product subject to this section shall include but not be limited to the good manufacturing practice requirements set forth in parts 210, 211, 600, 606, and 820 of this chapter. . . .

§ 601.4. Issuance and denial of license

(a) A biologics license shall be issued upon a determination by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research that the establishment(s) and the product meet the applicable requirements established in this chapter. A biologics license shall be valid until suspended or revoked.

(b) If the Commissioner determines that the establishment or product does not meet the requirements established in this chapter, the biologics license application shall be denied and the applicant shall be informed of the grounds for, and of an opportunity for a hearing on, the decision. If the applicant so requests, the Commissioner shall issue a notice of opportunity for hearing on the matter pursuant to §12.21(b) of this chapter.

§ 601.90. Scope

This subpart applies to certain biological products that have been studied for their safety and efficacy in ameliorating or preventing serious or life-threatening conditions caused by exposure to lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substances. This subpart applies only to those biological products for which: Definitive human efficacy studies cannot be conducted because it would be unethical to deliberately expose healthy human volunteers to a lethal or permanently disabling toxic biological, chemical, radiological, or nuclear substance; and field trials to study the product's efficacy after an accidental or hostile exposure have not been feasible. This subpart does not apply to products that can be approved based on efficacy standards described elsewhere in FDA's regulations (e.g., accelerated approval based on surrogate markers or clinical endpoints other than survival or irreversible morbidity), nor does it address the safety evaluation for the products to which it does apply.

§ 601.91. Approval based on evidence of effectiveness from studies in animals

(a) FDA may grant marketing approval for a biological product for which safety has been established and for which the requirements of § 601.90 are met based on adequate and well-controlled animal studies when the results of those animal studies establish that the biological product is reasonably likely to produce clinical benefit in humans. In assessing the sufficiency of animal data, the agency may take into account other data, including human data, available to the agency. FDA will rely on the evidence from studies in animals to provide substantial evidence of the effectiveness of these products only when:

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(1) There is a reasonably well-understood pathophysiological mechanism of the toxicity of the substance and its prevention or substantial reduction by the product;

(2) The effect is demonstrated in more than one animal species expected to react with a response predictive for humans, unless the effect is demonstrated in a single animal species that represents a sufficiently well-characterized animal model for predicting the response in humans;

(3) The animal study endpoint is clearly related to the desired benefit in humans, generally the enhancement of survival or prevention of major morbidity; and

(4) The data or information on the kinetics and pharmacodynamics of the product or other relevant data or information, in animals and humans, allows selection of an effective dose in humans.

(b) Approval under this subpart will be subject to three requirements:

(1) *Postmarketing studies*. The applicant must conduct postmarketing studies, such as field studies, to verify and describe the biological product's clinical benefit and to assess its safety when used as indicated when such studies are feasible and ethical. Such postmarketing studies would not be feasible until an exigency arises. When such studies are feasible, the applicant must conduct such studies with due diligence. Applicants must include as part of their application a plan or approach to postmarketing study commitments in the event such studies become ethical and feasible.

(2) *Approval with restrictions to ensure safe use*. If FDA concludes that a biological product shown to be effective under this subpart can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to ensure safe use of the biological product, commensurate with the specific safety concerns presented by the biological product, such as:

(i) Distribution restricted to certain facilities or health care practitioners with special training or experience;

(ii) Distribution conditioned on the performance of specified medical procedures, including medical followup; and

(iii) Distribution conditioned on specified recordkeeping requirements.

(3) *Information to be provided to patient recipients*. For biological products or specific indications approved under this subpart, applicants must prepare, as part of their proposed labeling, labeling to be provided to patient recipients. The patient labeling must explain that, for ethical or feasibility reasons, the biological product's approval was based on efficacy studies conducted in animals alone and must give the biological product's indication(s), directions for use (dosage and administration), contraindications, a description of any reasonably foreseeable risks, adverse reactions, anticipated benefits, drug interactions, and any other relevant information required by FDA at the time of approval. The patient labeling must be available with the product to be provided to patients prior to administration or dispensing of the biological product for the use approved under this subpart, if possible.

§ 601.95. Termination of requirements

If FDA determines after approval under this subpart that the requirements established in §§ 601.91(b)(2), 601.92, and 601.93 are no longer necessary for the safe and effective use of a biological product, FDA will so notify the applicant. Ordinarily, for biological products approved under § 601.91, these requirements will no longer apply when FDA determines that the postmarketing study verifies and describes the biological product's clinical benefit. For biological products approved under § 601.91, the restrictions would no longer apply when FDA determines that safe use of the biological product can be ensured

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through appropriate labeling. FDA also retains the discretion to remove specific postapproval requirements upon review of a petition submitted by the sponsor in accordance with § 10.30 of this chapter.

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Part 610—General biological products standards

§ 610.1. Tests prior to release required for each lot

No lot of any licensed product shall be released by the manufacturer prior to the completion of tests for conformity with standards applicable to such product. Each applicable test shall be made on each lot after completion of all processes of manufacture which may affect compliance with the standard to which the test applies. The results of all tests performed shall be considered in determining whether or not the test results meet the test objective, except that a test result may be disregarded when it is established that the test is invalid due to causes unrelated to the product.

§ 610.10. Potency

Tests for potency shall consist of either in vitro or in vivo tests, or both, which have been specifically designed for each product so as to indicate its potency in a manner adequate to satisfy the interpretation of potency given by the definition in §600.3(s) of this chapter.

§ 610.12. Sterility

(a) *The test*. Except as provided in paragraph (h) of this section, manufacturers of biological products must perform sterility testing of each lot of each biological product's final container material or other material, as appropriate and as approved in the biologics license application or supplement for that product.

(b) *Test requirements*.

(1) The sterility test must be appropriate to the material being tested such that the material does not interfere with or otherwise hinder the test.

(2) The sterility test must be validated to demonstrate that the test is capable of reliably and consistently detecting the presence of viable contaminating microorganisms.

(3) The sterility test and test components must be verified to demonstrate that the test method can consistently detect the presence of viable contaminating microorganisms.

. . . .

§ 610.13. Purity

Products shall be free of extraneous material except that which is unavoidable in the manufacturing process described in the approved biologics license application. In addition, products shall be tested as provided in paragraphs (a) and (b) of this section.

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SUBCHAPTER G—COSMETICS

Part 700—General

§ 700.3. Definitions

As used in this subchapter:

. . . .

(b) The term *cosmetic product* means a finished cosmetic the manufacture of which has been completed. Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V of the act.

(c) The term *flavor* means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.

(d) The term *fragrance* means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.

(e) The term *ingredient* means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product.

. . . .

(g) The term *chemical description* means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.

(h) The term *cosmetic raw* material means any ingredient, including an ingredient that is a mixture, which is used in the manufacture of a cosmetic product for commercial distribution and is supplied to a cosmetic product manufacturer, packer, or distributor by a cosmetic raw material manufacturer or supplier.

. . . .

§ 700.25. Tamper-resistant packaging requirements for cosmetic products

(a) *General*. Because most cosmetic liquid oral hygiene products and vaginal products are not now packaged in tamper-resistant retail packages, there is the opportunity for the malicious adulteration of those cosmetic products with health risks to individuals who unknowingly purchase adulterated products and with loss of consumer confidence in the security of cosmetic product packages. The Food and Drug Administration has the authority and responsibility under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-resistant packaging of cosmetic liquid oral hygiene products or products used vaginally that will improve the packaging security and help assure the safety of those products. Such a cosmetic product for retail sale that is not packaged in a tamper-resistant package or that is not properly labeled under this section is adulterated under section 601 of the act or misbranded under section 602 of the act, or both.

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§ 700.35. Cosmetics containing sunscreen ingredients.

(a) A product that includes the term "sunscreen" in its labeling or in any other way represents or suggests that it is intended to prevent, cure, treat, or mitigate disease or to affect a structure or function of the body comes within the definition of a drug in section 201(g)(1) of the act. Sunscreen active ingredients affect the structure or function of the body by absorbing, reflecting, or scattering the harmful, burning rays of the sun, thereby altering the normal physiological response to solar radiation. These ingredients also help to prevent diseases such as sunburn and may reduce the chance of premature skin aging, skin cancer, and other harmful effects due to the sun when used in conjunction with limiting sun exposure and wearing protective clothing. When consumers see the term "sunscreen" or similar sun protection terminology in the labeling of a product, they expect the product to protect them in some way from the harmful effects of the sun, irrespective of other labeling statements. Consequently, the use of the term "sunscreen" or similar sun protection terminology in a product's labeling generally causes the product to be subject to regulation as a drug. However, sunscreen ingredients may also be used in some products for nontherapeutic, nonphysiologic uses (e.g., as a color additive or to protect the color of the product). To avoid consumer misunderstanding, if a cosmetic product contains a sunscreen ingredient and uses the term "sunscreen" or similar sun protection terminology anywhere in its labeling, the term must be qualified by describing the cosmetic benefit provided by the sunscreen ingredient.

(b) The qualifying information required under paragraph (a) of this section shall appear prominently and conspicuously at least once in the labeling in conjunction with the term "sunscreen" or other similar sun protection terminology used in the labeling. For example: "Contains a sunscreen—to protect product color."

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Part 701—Cosmetic labeling

§ 701.1. Misbranding

(a) Among representations in labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

§ 701.3. Designation of ingredients

(a) The label on each package of a cosmetic shall bear a declaration of the name of each ingredient in descending order of predominance, except that fragrance or flavor may be listed as fragrance or flavor. An ingredient which is both fragrance and flavor shall be designated by each of the functions it performs unless such ingredient is identified by name. No ingredient may be designated as fragrance or flavor unless it is within the meaning of such term as commonly understood by consumers. Where one or more ingredients is accepted by the Food and Drug Administration as exempt from public disclosure pursuant to the procedure established in §720.8(a) of this chapter, in lieu of label declaration of identity the phrase "and other ingredients" may be used at the end of the ingredient declaration.

. . . .

§ 701.11. Identity labeling

(a) The principal display panel of a cosmetic in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The common or usual name of the cosmetic; or

(2) An appropriately descriptive name or, when the nature of the cosmetic is obvious, a fanciful name understood by the public to identify such cosmetic; or

(3) An appropriate illustration or vignette representing the intended cosmetic use.

(c) The statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

§ 701.12. Name and place of business of manufacturer, packer, or distributor

(a) The label of a cosmetic in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.

. . . .

(c) Where the cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such cosmetic; such as, "Manufactured for _____", "Distributed by _____", or any other wording that expresses the facts.

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§ 701.20. Detergent substances, other than soap, intended for use in cleansing the body

(a) In its definition of the term cosmetic, the Federal Food, Drug, and Cosmetic Act specifically excludes *soap*. The term *soap* is nowhere defined in the act. In administering the act, the Food and Drug Administration interprets the term "soap" to apply only to articles that meet the following conditions:

(1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and

(2) The product is labeled, sold, and represented only as soap.

(b) Products intended for cleansing the human body and which are not "soap" as set out in paragraph (a) of this section are "cosmetics," and accordingly they are subject to the requirements of the act and the regulations thereunder. For example, such a product in bar form is subject to the requirement, among others, that it shall bear a label containing an accurate statement of the weight of the bar in avoirdupois pounds and ounces, this statement to be prominently and conspicuously displayed so as to be likely to be read under the customary conditions of purchase and use.

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Part 710—Voluntary registration of cosmetic product establishments

§ 710.1. Who should register

The owner or operator of a cosmetic product establishment which is not exempt under §710.9 and engages in the manufacture or packaging of a cosmetic product is requested to register for each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in section 201(a)(1) of the act. No registration fee is required.

§ 710.9. Exemptions

The following classes of persons are not requested to register in accordance with this part 710 because the Commissioner has found that such registration is not justified:

(a) Beauty shops, cosmetologists, retailers, pharmacies, and other persons and organizations that compound cosmetic products at a single location and administer, dispense, or distribute them at retail from that location and who do not otherwise manufacture or package cosmetic products at that location.

(b) Physicians, hospitals, clinics, and public health agencies.

(c) Persons who manufacture, prepare, compound, or process cosmetic products solely for use in research, pilot plant production, teaching, or chemical analysis, and who do not sell these products.

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Part 720—Voluntary filing of cosmetic product ingredient composition statements

§ 720.1. Who should file

Either the manufacturer, packer, or distributor of a cosmetic product is requested to file Form FDA 2512 ("Cosmetic Product Ingredient Statement"), whether or not the cosmetic product enters interstate commerce. This request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as defined in section 201(a)(1) of the Federal Food, Drug, and Cosmetic Act. No filing fee is required.

§ 720.4. Information requested about cosmetic products

(a) Form FDA-2512 requests information on:

(1) The name and address, including post office ZIP code of the person (manufacturer, packer, or distributor) designated on the label of the product.

(2) The name and address, including post office ZIP code, of the manufacturer or packer of the product if different from the person designated on the label of the product, when the manufacturer or packer submits the information requested under this paragraph.

(3) The brand name or names of the cosmetic product.

(4) The cosmetic product category or categories.

(5) The ingredients in the product.

. . . .

(d) Ingredients in the product should be listed as follows:

(1) A list of each ingredient of the cosmetic product in descending order of predominance by weight (except that the fragrance and/or flavor may be designated as such without naming each individual ingredient when the manufacturer or supplier of the fragrance and/or flavor refuses to disclose ingredient data).

(2) An ingredient should be listed by the name adopted by the Food and Drug Administration (FDA) for the ingredient pursuant to §701.3(c) of this chapter.

(3) In the absence of a name adopted by FDA pursuant to §701.3(c) of this chapter, its common or usual name, if it has one, or its chemical or technical name should be listed.

(4) If an ingredient is a mixture, each ingredient of the mixture should be listed in accordance with paragraphs (d)(2) and (d)(3) of this section, unless such mixture is a formulation voluntarily registered on Form FDA 2512, in which case such mixture should be identified as "fragrance," "flavor," "fragrance and flavor" or "base formulation," as appropriate, and by stating its FDA-assigned cosmetic product ingredient statement number.

(5) When the manufacturer or supplier of a fragrance and/or flavor refuses to disclose ingredient data, the fragrance and/or flavor should be listed as such. The nonconfidential listing of the product name and/or trade name or name of the manufacturer or supplier of each proprietary fragrance and/or flavor mixture is optional.

(e) A separate Form FDA-2512 should be filed for each different formulation of a cosmetic product.

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However, except for the hair coloring preparations listed in paragraph (c)(6) of this section for which a statement for each shade of such product is required, a single Form FDA-2512 may be filed for two or more shades of a cosmetic product where only the amounts of the color additive ingredient used are varied or in the case of flavors and fragrances where only the amounts of the flavors and fragrances used are varied.

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§ 720.9. Misbranding by reference to filing or to statement number

The filing of Form FDA 2512 or assignment of a number to the statement does not in any way denote approval by the Food and Drug Administration of the firm or the product. Any representation in labeling or advertising that creates an impression of official approval because of such filing or such number will be considered misleading.

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Part 740—Cosmetic product warning statements

§ 740.1. Establishment of warning statements

(a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

(b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

§ 740.10. Labeling of cosmetic products for which adequate substantiation of safety has not been obtained

(a) Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

Warning—The safety of this product has not been determined.

(b) An ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product if:

(1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information;

(2) The new information does not demonstrate a hazard to human health; and

(3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product.

(c) Paragraph (b) of this section does not constitute an exemption to the adulteration provisions of the Act or to any other requirement in the Act or this chapter.

§ 740.17. Foaming detergent bath products

(a) For the purpose of this section, a foaming detergent bath product is any product intended to be added to a bath for the purpose of producing foam that contains a surface-active agent serving as a detergent or foaming ingredient.

(b) The label of foaming detergent bath products within the meaning of paragraph (a) of this section, except for those products that are labeled as intended for use exclusively by adults, shall bear adequate directions for safe use and the following caution:

Caution—Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

(c) In the case of products intended for use by children, the phrase "except under adult supervision" may be added at the end of the last sentence in the caution required by paragraph (b) of this section.

§ 740.19. Suntanning preparations

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The labeling of suntanning preparations that do not contain a sunscreen ingredient must display the following warning: "Warning—This product does not contain a sunscreen and does not protect against sunburn. Repeated exposure of unprotected skin while tanning may increase the risk of skin aging, skin cancer, and other harmful effects to the skin even if you do not burn." For purposes of this section, the term "suntanning preparations" includes gels, creams, liquids, and other topical products that are intended to provide cosmetic effects on the skin while tanning through exposure to UV radiation (e.g., moisturizing or conditioning products), or to give the appearance of a tan by imparting color to the skin through the application of approved color additives (e.g., dihydroxyacetone) without the need for exposure to UV radiation. The term "suntanning preparations" does not include products intended to provide sun protection or otherwise intended to affect the structure or any function of the body.

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SUBCHAPTER H—MEDICAL DEVICES

Part 807—Establishment registration and device listing for manufacturers and initial importers of devices

§ 807.81. When a premarket notification submission is required

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to §807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

(1) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to,

(i) a device in commercial distribution before May 28, 1976, or

(ii) a device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(2) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a)(1) of this section.

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

(b)

(1) A premarket notification under this subpart is not required for a device for which:

(i) A premarket approval application under section 515 of the act, or for which a petition to reclassify under section 513(f)(2) of the act, is pending before the Food and Drug Administration, or

(ii) There is a predetermined change control plan (PCCP) cleared under section 515C of the act, provided that the change is consistent with the PCCP.

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§ 807.85. Exemption from premarket notification

(a) A custom device is exempt from premarket notification requirements of this subpart if the device is within the meaning of section 520(b) of the Federal Food, Drug, and Cosmetic Act.

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(1) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

(2) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

(b) A distributor who places a device into commercial distribution for the first time under his own name and a repackager who places his own name on a device and does not change any other labeling or otherwise affect the device shall be exempted from the premarket notification requirements of this subpart if:

(1) The device was in commercial distribution before May 28, 1976; or

(2) A premarket notification submission was filed by another person.

§ 807.87. Information required in a premarket notification submission

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in §807.92 or a 510(k) statement as described in §807.93.

(i) A financial certification or disclosure statement or both, as required by part 54 of this chapter.

(j) For a submission supported by clinical data:

(1) If the data are from clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with applicable requirements in the protection of

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human subjects regulations in part 50 of this chapter, the institutional review boards regulations in part 56 of this chapter, or was not subject to the regulations under §56.104 or §56.105, and the investigational device exemptions regulations in part 812 of this chapter, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(2) If the data are from clinical investigations conducted outside the United States, the requirements under §812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in §812.28(a) of this chapter, include either a waiver request in accordance with §812.28(c) of the chapter or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected.

(k) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in §807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(l) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(m) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

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§ 807.90. Format of a premarket notification submission

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§ 807.92. Content and format of a 510(k) summary

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and

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complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."

(d) Any other information reasonably deemed necessary by the agency.

§ 807.97. Misbranding by reference to premarket notification

Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

§ 807.100. FDA action on a premarket notification

(a) After review of a premarket notification, FDA will:

(1) Issue an order declaring the device to be substantially equivalent to a legally marketed predicate device;

(2) Issue an order declaring the device to be not substantially equivalent to any legally marketed predicate device;

(3) Request additional information; or

(4) Withhold the decision until a certification or disclosure statement is submitted to FDA under part 54 of this chapter.

(5) Advise the applicant that the premarket notification is not required. Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.

(b) FDA will determine that a device is substantially equivalent to a predicate device using the following criteria:

(1) The device has the same intended use as the predicate device; and

(2) The device:

(i) Has the same technological characteristics as the predicate device; or

(ii)

(A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;

(B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the

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Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device; and

(C) Does not raise different questions of safety and effectiveness than the predicate device.

(3) The predicate device has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.

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Part 808—Exemptions from federal preemption of state and local medical device requirements

§808.1. Scope

(a) *Introduction*. This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) *General rule for State and local requirements respecting devices*. Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) *Exempting from preemption certain State or local requirements respecting devices*. Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) *Meaning of "requirements applicable to a device."* State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

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(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)

(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy Act of 1954 (42 U.S.C. 2011 note), as amended, Subchapter C—Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968), and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

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(e) *Determination of equivalence or difference of requirements applicable to a device*. It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) *Applicability of Federal requirements respecting devices*. The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

(g) *Exemptions not applicable to certain State or local government requirements specifically related to hearing products*. An exemption under this part shall not apply to any State or local government law, regulation, order, or other requirement specifically related to hearing products, including any requirement for the supervision, prescription, or other order, involvement, or intervention of a licensed person for consumers to access over-the-counter hearing aids, that:

(1) Would restrict or interfere with the servicing, marketing, sale, dispensing, use, customer support, or distribution of over-the-counter hearing aids, as defined under section 520(q) of the Federal Food, Drug, and Cosmetic Act, through in-person transactions, by mail, or online; and

(2) Is different from, in addition to, or otherwise not identical to, the regulations issued under section 709(b) of the FDA Reauthorization Act of 2017.

§ 808.3. Definitions

Compelling local conditions includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

More stringent refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act.

Political subdivision or locality means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

State means any State or Territory of the United States, including but not limited to, the District of Columbia and the Commonwealth of Puerto Rico.

Substantially identical to refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.5. Advisory opinions

(a) Any State, political subdivision, or other interested person may request an advisory opinion from the Commissioner with respect to any general matter concerning preemption of State or local device

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requirements or with respect to whether the Food and Drug Administration regards particular State or local requirements, or proposed requirements, as preempted.

(1) Such an advisory opinion may be requested and may be granted in accordance with §10.85 of this chapter.

(2) The Food and Drug Administration, in its discretion and after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under §808.20.

(b) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations:

(1) A requirement with respect to a device for which an application for exemption from preemption has been submitted under §808.20 is not preempted by section 521(a) of the Federal Food, Drug, and Cosmetic Act because it is:

(i) Equal to or substantially identical to a requirement under the Federal Food, Drug, and Cosmetic Act applicable to the device, or

(ii) is not a requirement within the meaning of section 521 of the Federal Food, Drug, and Cosmetic Act and therefore is not preempted;

(2) A proposed State or local requirement with respect to a device is not eligible for exemption from preemption because the State or local requirement has not been issued in final form. In such a case, the advisory opinion may indicate whether the proposed requirement would be preempted and, if it would be preempted, whether the Food and Drug Administration would propose to grant an exemption from preemption;

(3) Issuance of such an advisory opinion is in the public interest.

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Part 814—Premarket approval of medical devices

§ 814.1. Scope

(a) This section implements sections 515 and 515A of the act by providing procedures for the premarket approval of medical devices intended for human use.

. . . .

(c) This part applies to any class III medical device, unless exempt under section 520(g) of the act, that:

(1) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II; or

(2) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under section 515(b) of the act; or

(3) Was regulated by FDA as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by section 520(1) of the act.

(d) This part amends the conditions to approval for any PMA approved before the effective date of this part. Any condition to approval for an approved PMA that is inconsistent with this part is revoked. Any condition to approval for an approved PMA that is consistent with this part remains in effect.

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Part 860—Medical device classification procedures

Subpart A—General

§ 860.1. Scope

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

§ 860.3. Definitions

For the purposes of this part:

Class means one of the three categories of regulatory control for medical devices, defined as follows:

Class I means the class of devices that are subject only to the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act. A device is in class I if:

(1) General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or

(2) There is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

Class II means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, which are necessary to provide adequate assurance of safety and effectiveness, and describe how such controls provide such assurance.

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Class III means the class of devices for which premarket approval is or will be required in accordance with section 515 of the Federal Food, Drug, and Cosmetic Act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness, or that application of special controls described in the definition of "Class II" in this section in addition to general controls, would provide such assurance, and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

Classification panel means one of the several advisory committees established by the Commissioner under section 513 of the Federal Food, Drug, and Cosmetic Act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the Federal Food, Drug, and Cosmetic Act or by the Commissioner.

Classification regulation means a section under parts 862 through 892 of this chapter that contains the identification (general description and intended use) and classification (class I, II or III) of a single device type or more than one related device type(s).

. . . .*De Novo request* means any submission under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act for a medical device, requesting classification into class I or class II, including all information submitted with or incorporated by reference therein.

. . . .

General controls mean the controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration, listing, and premarket notification), 516 (banned devices), 518 (notification and other remedies), 519 (records, reports, and unique device identification), and 520 (general provisions) of the Federal Food, Drug, and Cosmetic Act.

Generic type of device means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

Implant means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise to protect human health.

Life-supporting or life-sustaining device means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

Petition means a submission seeking reclassification of a device in accordance with § 860.123.

Special controls mean the controls necessary to provide reasonable assurance of safety and effectiveness for a generic type of device that is class II. Special controls include performance standards, performance testing, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the Federal Food, Drug, and Cosmetic Act), recommendations, and other appropriate actions, as the Commissioner deems necessary to provide such assurance.

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§ 860.7. Determination of safety and effectiveness

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

. . . .

(c)

(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device with questionable safety or effectiveness.

(d)

(1) There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, nonclinical investigations, and analytical studies for in vitro diagnostic devices.

(e)

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(1) There is reasonable assurance that a device is effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

. . . .

Subpart B—Classification

§ 860.84. Classification procedures for "preamendments devices"

(a) This subpart sets forth the procedures for the original classification of a generic type of device that was in commercial distribution before May 28, 1976. Such a device will be classified by regulation into either class I (general controls), class II (special controls) or class III (premarket approval), depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device (§860.3(c)). This subpart does not apply to a device that is classified into class III by statute under section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act because the Food and Drug Administration has determined that the device is not "substantially equivalent" to any device subject to this subpart or under section 520(l)(1) of the Federal Food, Drug, and Cosmetic Act because the device was regarded previously as a new drug. In classifying a preamendments device to which this section applies, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

. . . .

Subpart C—Reclassification

§ 860.120. General

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in §860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all devices within the same generic type.

. . . .

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Part 868—Anesthesiology devices

§ 868.5895. Continuous ventilator

(a) *Identification*. A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) *Classification*. Class II (performance standards).

§ 868.5905. Noncontinuous ventilator (IPPB)

(a) *Identification*. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing.

(b) *Classification*. Class II (performance standards).

§ 868.5915. Manual emergency ventilator

(a) *Identification*. A manual emergency ventilator is a device, usually incorporating a bag and valve, intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification*. Class II (performance standards).

§ 868.5925. Powered emergency ventilator

(a) *Identification*. A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

(b) *Classification*. Class II (performance standards).

§ 868.5975. Ventilator tubing

(a) *Identification*. Ventilator tubing is a device intended for use as a conduit for gases between a ventilator and a patient during ventilation of the patient.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §868.9.

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Part 870—Cardiovascular devices

§ 870.1200 Diagnostic intravascular catheter.

(a) *Identification*. An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

(b) *Classification*. Class II (performance standards).

§ 870.1875 Stethoscope.

(a) Manual stethoscope—

(1) *Identification*. A manual stethoscope is a mechanical device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §870.9.

(b) Electronic stethoscope—

(1) *Identification*. An electronic stethoscope is an electrically amplified device used to project the sounds associated with the heart, arteries, and veins and other internal organs.

(2) *Classification*. Class II (special controls). The device, when it is a lung sound monitor, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §870.9.

§ 870.3610 Implantable pacemaker pulse generator.

(a) *Identification*. An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This device may include triggered, inhibited, and asynchronous modes and is implanted in the human body.

(b) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of PDP is required*. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 20, 2012, for any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976, or that has, on or before September 20, 2012, been found to be substantially equivalent to any implantable pacemaker pulse generator device that was in commercial distribution before May 28, 1976. Any other implantable pacemaker pulse generator device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

§ 870.3620 Pacemaker lead adaptor.

(a) *Identification*. A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled "Guidance for the Submission of Research and Marketing Applications for Permanent Pacemaker Leads and for Pacemaker Lead Adaptor 510(k) Submissions."

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Part 872—Dental devices

§ 872.6855 Manual toothbrush.

(a) *Identification*. A manual toothbrush is a device composed of a shaft with either natural or synthetic bristles at one end intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, with respect to general requirements concerning records, and §820.198, with respect to complaint files.

§ 872.6865 Powered toothbrush.

(a) *Identification*. A powered toothbrush is an AC-powered or battery-powered device that consists of a handle containing a motor that provides mechanical movement to a brush intended to be applied to the teeth. The device is intended to remove adherent plaque and food debris from the teeth to reduce tooth decay.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §872.9.

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Part 878—General and plastic surgery devices

§ 878.3530. Silicone inflatable breast prosthesis

(a) *Identification*. A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(b) *Classification*. Class III.

(c) *Date PMA or notice of completion of a PDP is required*. A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 17, 1999, for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before November 17, 1999, been found to be substantially equivalent to a silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone inflatable breast prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

§ 878.3540. Silicone gel-filled breast prosthesis

(a) *Identification*—

(1) Single-lumen silicone gel-filled breast prosthesis. A single-lumen silicone gel-filled breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The shell either contains a fixed amount cross-linked polymerized silicone gel, filler, and stabilizers or is filled to the desired size with injectable silicone gel at time of implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(2) Double-lumen silicone gel-filled breast prosthesis. A double lumen silicone gel-filled breast prosthesis is a silicone rubber inner shell and a silicone rubber outer shell, both shells made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane. The inner shell contains fixed amounts of cross-linked polymerized silicone gel, fillers, and stabilizers. The outer shell is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

(3) Polyurethane covered silicone gel-filled breast prosthesis. A polyurethane covered silicone gel-filled breast prosthesis is an inner silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, with an outer silicone adhesive layer and an outer covering of polyurethane; contained within the inner shell is a fixed amount of cross-linked polymerized silicone gel, fillers, and stabilizers and an inert support structure compartmentalizing the silicone gel. The device is intended to be implanted to augment or reconstruct the female breast.

(b) *Classification*. Class III.

(c) Date premarket approval application (PMA) is required. A PMA is required to be filed with the Food and Drug Administration on or before July 9, 1991 for any silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976, or that has on or before July 9, 1991 been found to be substantially equivalent to a silicone gel-filled breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone gel-filled breast prosthesis shall have an approved PMA in effect before being placed in commercial distribution.

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§ 878.4040 Surgical apparel.

(a) *Identification*. Surgical apparel are devices that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Examples include surgical caps, hoods, masks, gowns, operating room shoes and shoe covers, and isolation masks and gowns. Surgical suits and dresses, commonly known as scrub suits, are excluded.

(b) *Classification*.

(1) Class II (special controls) for surgical gowns and surgical masks. A surgical N95 respirator or N95 filtering facepiece respirator is not exempt if it is intended to prevent specific diseases or infections, or it is labeled or otherwise represented as filtering surgical smoke or plumes, filtering specific amounts of viruses or bacteria, reducing the amount of and/or killing viruses, bacteria, or fungi, or affecting allergenicity, or it contains coating technologies unrelated to filtration (e.g., to reduce and or kill microorganisms). Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §878.9, and the following conditions for exemption:

(i) The user contacting components of the device must be demonstrated to be biocompatible.

(ii) Analysis and nonclinical testing must:

(A) Characterize flammability and be demonstrated to be appropriate for the intended environment of use; and

(B) Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.

(iii) NIOSH approved under its regulation.

(2) Class I (general controls) for surgical apparel other than surgical gowns and surgical masks. The class I device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to [various exceptions specified in] §878.9.

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Part 880—General hospital and personal use devices

§ 880.6260. Filtering facepiece respirator for use by the general public in public health medical emergencies

(a) *Identification*. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

(b) *Classification*. Class II (special controls). The special controls are:

(1) Certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.

(2) The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for use by the General Public in Public Health Medical Emergencies." . . .

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Part 890—Physical medicine devices

§ 890.3075 Cane.

(a) *Identification*. A cane is a device intended for medical purposes that is used to provide minimal weight support while walking. Examples of canes include the following: A standard cane, a forearm cane, and a cane with a tripod, quad, or retractable stud on the ground end.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records and §820.198, regarding complaint files.

§ 890.3150 Crutch.

(a) *Identification*. A crutch is a device intended for medical purposes for use by disabled persons to provide minimal to moderate weight support while walking.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in §890.9. The device is also exempt from the current good manufacturing practice requirements of the quality system regulation in part 820 of this chapter, with the exception of §820.180, regarding general requirements concerning records and §820.198, regarding complaint files.

§ 890.3850 Mechanical wheelchair.

(a) *Identification*. A mechanical wheelchair is a manually operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification*. Class I (general controls).

§ 890.3860 Powered wheelchair.

(a) *Identification*. A powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position.

(b) *Classification*. Class II (performance standards).

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Part 892—Radiology devices

§ 892.1000 Magnetic resonance diagnostic device.

(a) *Identification*. A magnetic resonance diagnostic device is intended for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information).

(b) *Classification*. Class II (special controls). A magnetic resonance imaging disposable kit intended for use with a magnetic resonance diagnostic device only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §892.9.

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Part 895—Banned devices

Subpart A—General Provisions

§ 895.1 Scope.

(a) This part describes the procedures by which the Commissioner may institute proceedings to make a device intended for human use that presents substantial deception or an unreasonable and substantial risk of illness or injury a banned device.

(b) This part applies to any "device", as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (act) that is intended for human use.

(c) A device that is made a banned device in accordance with this part is adulterated under section 501(g) of the act. A restricted device that is banned may also be misbranded under section 502(q) of the act.

(d) Although this part does not cover devices intended for animal use, the manufacturer, distributor, importer, or any other person(s) responsible for the labeling of the device that is banned cannot avoid the ban by relabeling the device for veterinary use. A device that has been banned from human use but that also has a valid veterinary use may be marketed for use as a veterinary device only under the following conditions: The device shall comply with all requirements applicable to veterinary devices under the Federal Food, Drug, and Cosmetic Act and this chapter, and the label for the device shall bear the following statement: "For Veterinary Use Only. Caution: Federal law prohibits the distribution of this device for human use." A device so labeled, however, that is determined by the Food and Drug Administration to be intended for human use, will be considered to be a banned device. In determining whether such a device is intended for human use, the Food and Drug Administration will consider, among other things, the ultimate destination of the device.

§ 895.20 General.

The Commissioner may initiate a proceeding to make a device a banned device whenever the Commissioner finds, on the basis of all available data and information, that the device presents substantial deception or an unreasonable and substantial risk of illness or injury that the Commissioner determines cannot be, or has not been, corrected or eliminated by labeling or by a change in labeling, or by a change in advertising if the device is a restricted device.

. . . .

Subpart B—Listing of Banned Devices

§ 895.101. Prosthetic hair fibers

Prosthetic hair fibers are devices intended for implantation into the human scalp to simulate natural hair or conceal baldness. Prosthetic hair fibers may consist of various materials; for example, synthetic fibers, such as modacrylic, polyacrylic, and polyester; and natural fibers, such as processed human hair. Excluded from the banned device are natural hair transplants, in which a person's hair and its surrounding tissue are surgically removed from one location on the person's scalp and then grafted onto another area of the person's scalp.

§ 895.102. Powdered surgeon's glove

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(a) *Identification*. A powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination. A powdered surgeon's glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

§ 895.103. Powdered patient examination glove

(a) *Identification*. A powdered patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. A powdered patient examination glove incorporates powder for purposes other than manufacturing.

(b) [Reserved]

§ 895.104. Absorbable powder for lubricating a surgeon's glove

Absorbable powder for lubricating a surgeon's glove is a powder made from cornstarch that meets the specifications for absorbable powder in the United States Pharmacopeia (U.S.P.) and that is intended to be used to lubricate the surgeon's hand before putting on a surgeon's glove. The device is absorbable through biological degradation.

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Part 898—Performance standard for electrode lead wires and patient cables

§ 898.11. Applicability

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in §898.12.

§ 898.12. Performance standard

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601-1: Medical Electrical Equipment

601-1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13. Compliance dates

The dates for compliance with the standard set forth in §898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998 *[chart of devices omitted].*

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

§ 898.14. Exemptions and variances

(a) A request for an exemption or variance shall be submitted in the form of a petition under §10.30 of this chapter and shall comply with the requirements set out therein. . . .

EFFECTIVE DATE NOTE: At 62 FR 25477, May 9, 1997, §898.14 was stayed pending Office of Management and Budget approval of information collection and recordkeeping requirements.

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SUBCHAPTER K—TOBACCO PRODUCTS

Part 1100—Tobacco products subject to FDA authority

§ 1100.1. Scope

In addition to FDA's authority over cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco, FDA deems all other products meeting the definition of *tobacco product* under section 201(d) of the Federal Food, Drug, and Cosmetic Act, except accessories of such other tobacco products, to be subject to the Federal Food, Drug, and Cosmetic Act.

§ 1100.2. Requirements

Cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco are subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. FDA has deemed all other tobacco products, except accessories of such other tobacco products, subject to chapter IX of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

§ 1100.3. Definitions

For the purposes of this part:

Accessory means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:

(1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or

(2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but

(i) Solely controls moisture and/or temperature of a stored tobacco product; or

(ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

Component or *part* means any software or assembly of materials intended or reasonably expected:

(1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

. . . .

Tobacco product. As stated in section 201(rr) of the Federal Food, Drug, and Cosmetic Act in relevant part, a tobacco product:

(1) Means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and

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(2) Does not mean an article that is a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act, a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act, or a combination product described in section 503(g) of the Federal Food, Drug, and Cosmetic Act.

§1100.5. Exclusion from tobacco regulation

If a product made or derived from tobacco that is intended for human consumption is intended for use for any of the purposes described in paragraph (a) or (b) of this section, the product is not a tobacco product as defined in section 201(rr) of the Federal Food, Drug, and Cosmetic Act and will be subject to regulation as a drug, device, or combination product.

(a) The product is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, including use in the cure or treatment of nicotine addiction (e.g., smoking cessation), relapse prevention, or relief of nicotine withdrawal symptoms;

(b) The product is intended to affect the structure or any function of the body in any way that is different from effects related to nicotine that were commonly and legally claimed in the marketing of cigarettes and smokeless tobacco products prior to March 21, 2000.

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Part 1140— Cigarettes, smokeless tobacco, and covered tobacco products

Subpart A—General Provisions

§ 1140.1. Scope

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products. Section 1140.16(d) sets out restrictions on the distribution of free samples for cigarettes, smokeless tobacco, and other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes, smokeless tobacco, covered tobacco products, or other tobacco products renders the product misbranded under the Federal Food, Drug, and Cosmetic Act.

. . . .

§ 1140.2. Purpose

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes, smokeless tobacco, and covered tobacco products in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

. . . .

Subpart B—Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

§ 1140.10. General responsibilities of manufacturers, distributors, and retailers

Each manufacturer, distributor, importer, and retailer is responsible for ensuring that the cigarettes, smokeless tobacco, or covered tobacco products it manufactures, labels, advertises, packages, distributes, imports, sells, or otherwise holds for sale comply with all applicable requirements under this part.

. . . .

§ 1140.16. Conditions of manufacture, sale, and distribution

(a) *Restriction on product names*. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) *Minimum cigarette package size*. Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) *Vending machines, self-service displays, mail-order sales, and other "impersonal" modes of sale*.

(1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

. . . .

Subpart D—Labeling and Advertising

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§ 1140.30. Scope of permissible forms of labeling and advertising

(a)

(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. . . .

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

§ 1140.32. Format and content requirements for labeling and advertising

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self- service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

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SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

Part 1270—Human tissue intended for transplantation

[revoked by 87 FR 2045 (2022-01-13)][10]

§ 1270.1. Scope

(a) The regulations in this part apply to human tissue and to establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue.

(b) Regulations in this chapter as they apply to drugs, biologics, devices, or other FDA-regulated commodities do not apply to human tissue, except as specified in this part.

(c) Regulations in this chapter do not apply to autologous human tissue.

(d) Regulations in this chapter do not apply to hospitals or other clinical facilities that receive and store human tissue only for transplantation within the same facility.

§ 1270.3. Definitions

. . . .

(j) *Human tissue*, for the purpose of this part means any tissue derived from a human body and recovered before May 25, 2005, which:

(1) Is intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease;

(2) Is recovered, processed, stored, or distributed by methods that do not change tissue function or characteristics;

(3) Is not currently regulated as a human drug, biological product, or medical device;

(4) Excludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ; and

---

[10] This regulation was revoked as obsolete by the Federal Register document listed above. FDA summarized the purpose of its decision to revoke Part 1271 as follows:

> These regulations apply to certain tissues recovered prior to May 25, 2005. The Agency does not believe there are currently any tissues intended for transplantation remaining in inventory that were recovered prior to this date and that would be subject to these regulations. Therefore, the regulations under this part are outdated and obsolete. All HCT/Ps recovered on or after May 25, 2005, are subject to the regulations under part 1271 (21 CFR part 1271), "Human Cells, Tissues, and Cellular and Tissue-Based Products."

87 FR 2045, 2046 (2022-01-13). Because this regulation is listed as assigned reading in the casebook, its text is retained here rather than removed entirely.

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(5) Excludes semen or other reproductive tissue, human milk, and bone marrow.

. . . .

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Part 1271—Human cells, tissues, and cellular and tissue-based products

Subpart A—General Provisions

§ 1271.1. What are the purpose and scope of this part?

(a) *Purpose*. The purpose of this part, in conjunction with . . . is to create an electronic registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P's) and to establish donor-eligibility, current good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.

(b) *Scope*.

(1) If you are an establishment that manufactures HCT/P's that are regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act), this part requires you to register and list your HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research and to comply with the other requirements contained in this part, whether or not the HCT/P enters into interstate commerce. Those HCT/P's that are regulated solely under the authority of section 361 of the PHS Act are described in §1271.10.

(2) If you are an establishment that manufactures HCT/P's that are regulated as drugs, devices and/or biological products under section 351 of the PHS Act and/or the Federal Food, Drug, and Cosmetic Act, [various sections] of this chapter require you to register and list your HCT/P's following the procedures in part 207 (if a drug and/or biological product) of this chapter or part 807 (if a device) of this chapter. [Various sections] of this chapter require you to comply with the donor-eligibility procedures in subpart C of this part and the current good tissue practice procedures in subpart D of this part, in addition to all other applicable regulations.

§ 1271.3. How does FDA define important terms in this part?

The following definitions apply only to this part:

(a) *Autologous use* means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.

. . . .

(c) *Homologous use* means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

(d) *Human cells, tissues, or cellular or tissue-based products (HCT/Ps)* means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. The following articles are not considered HCT/Ps:

(1) Vascularized human organs for transplantation;

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(2) Whole blood or blood components or blood derivative products subject to listing under parts 607 and 207 of this chapter, respectively;

(3) Secreted or extracted human products, such as milk, collagen, and cell factors; except that semen is considered an HCT/P;

(4) Minimally manipulated bone marrow for homologous use and not combined with another article (except for water, crystalloids, or a sterilizing, preserving, or storage agent, if the addition of the agent does not raise new clinical safety concerns with respect to the bone marrow);

(5) Ancillary products used in the manufacture of HCT/P;

(6) Cells, tissues, and organs derived from animals other than humans; and

(7) In vitro diagnostic products as defined in §809.3(a) of this chapter.

(8) Blood vessels recovered with an organ, as defined in 42 CFR 121.2, that are intended for use in organ transplantation and labeled "For use in organ transplantation only."

. . . .

(m) *Donor* means a person, living or dead, who is the source of cells or tissue for an HCT/P.

. . . .

(r) *Relevant communicable disease agent or disease* means:

(1)

(i) For all human cells and tissues, a communicable disease or disease agent listed as follows:

(A) Human immunodeficiency virus, types 1 and 2;

(B) Hepatitis B virus;

(C) Hepatitis C virus;

(D) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease; and

(E) Treponema pallidum.

(ii) For viable, leukocyte-rich cells and tissues, a cell-associated disease agent or disease listed as follows:

(A) Human T-lymphotropic virus, type I; and

(B) Human T-lymphotropic virus, type II.

(iii) For reproductive cells or tissues, a disease agent or disease of the genitourinary tract listed as follows:

(A) Chlamydia trachomatis; and

(B) Neisseria gonorrhea.

(2) A disease agent or disease not listed in paragraph (r)(1) of this section:

(i) For which there may be a risk of transmission by an HCT/P, either to the recipient of the HCT/P or to those people who may handle or otherwise come in contact with it, such as medical personnel, because the disease agent or disease:

(A) Is potentially transmissible by an HCT/P and

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(B) Either of the following applies:

(1) The disease agent or disease has sufficient incidence and/or prevalence to affect the potential donor population, or

(2) The disease agent or disease may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection;

(ii) That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure; and

(iii) For which appropriate screening measures have been developed and/or an appropriate screening test for donor specimens has been licensed, approved, or cleared for such use by FDA and is available.

. . . .

(s) *Relevant medical records* means a collection of documents that includes a current donor medical history interview; a current report of the physical assessment of a cadaveric donor or the physical examination of a living donor; and, if available, the following:

(1) Laboratory test results (other than results of testing for relevant communicable disease agents required under this subpart);

(2) Medical records;

(3) Coroner and autopsy reports; and

(4) Records or other information received from any source pertaining to risk factors for relevant communicable disease (e.g., social behavior, clinical signs and symptoms of relevant communicable disease, and treatments related to medical conditions suggestive of risk for relevant communicable disease).

. . . .

§ 1271.10. Are my HCT/P's regulated solely under section 361 of the PHS Act and the regulations in this part, and if so what must I do?

(a) An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in this part if it meets all of the following criteria:

(1) The HCT/P is minimally manipulated;

(2) The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;

(3) The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

(4) Either:

(i) The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

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(ii) The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

(a) Is for autologous use;

(b) Is for allogeneic use in a first-degree or second-degree blood relative; or

(c) Is for reproductive use.

(b) If you are a domestic or foreign establishment that manufactures an HCT/P described in paragraph (a) of this section:

(1) You must register with FDA;

(2) You must submit to FDA a list of each HCT/P manufactured; and

(3) You must comply with the other requirements contained in this part.

§ 1271.15. Are there any exceptions from the requirements of this part?

(a) You are not required to comply with the requirements of this part if you are an establishment that uses HCT/P's solely for nonclinical scientific or educational purposes.

(b) You are not required to comply with the requirements of this part if you are an establishment that removes HCT/P's from an individual and implants such HCT/P's into the same individual during the same surgical procedure.

(c) You are not required to comply with the requirements of this part if you are a carrier who accepts, receives, carries, or delivers HCT/P's in the usual course of business as a carrier.

(d) You are not required to comply with the requirements of this part if you are an establishment that does not recover, screen, test, process, label, package, or distribute, but only receives or stores HCT/P's solely for implantation, transplantation, infusion, or transfer within your facility.

(e) You are not required to comply with the requirements of this part if you are an establishment that only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor.

(f) You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.

§ 1271.20. If my HCT/P's do not meet the criteria in §1271.10, and I do not qualify for any of the exceptions in §1271.15, what regulations apply?

If you are an establishment that manufactures an HCT/P that does not meet the criteria set out in §1271.10(a), and you do not qualify for any of the exceptions in §1271.15, your HCT/P will be regulated as a drug, device, and/or biological product under the act and/or section 351 of the PHS Act, and applicable regulations in title 21, chapter I. Applicable regulations include, but are not limited to [various regulations listed] which require you to follow the procedures in subparts C and D of this part.

. . . .

Subpart C—Donor Eligibility

§ 1271.45. What requirements does this subpart contain?

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(a) *General*. This subpart sets out requirements for determining donor eligibility, including donor screening and testing. The requirements contained in this subpart are a component of current good tissue practice (CGTP) requirements. Other CGTP requirements are set out in subpart D of this part.

(b) *Donor-eligibility determination required*. A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under §1271.90. In the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor.

(c) *Prohibition on use*. An HCT/P must not be implanted, transplanted, infused, or transferred until the donor has been determined to be eligible, except as provided under §§1271.60(d), 1271.65(b), and 1271.90 of this subpart.

(d) *Applicability of requirements*. If you are an establishment that performs any function described in this subpart, you must comply with the requirements contained in this subpart that are applicable to that function.

. . . .

Subpart D—Current Good Tissue Practice

§ 1271.145. Prevention of the introduction, transmission, or spread of communicable diseases

You must recover, process, store, label, package, and distribute HCT/Ps, and screen and test cell and tissue donors, in a way that prevents the introduction, transmission, or spread of communicable diseases.

§ 1271.150. Current good tissue practice requirements

(a) *General*. This subpart D and subpart C of this part set forth current good tissue practice (CGTP) requirements. You must follow CGTP requirements to prevent the introduction, transmission, or spread of communicable diseases by HCT/Ps (e.g., by ensuring that the HCT/Ps do not contain communicable disease agents, that they are not contaminated, and that they do not become contaminated during manufacturing). Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents. CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution. The CGTP provisions specifically governing determinations of donor eligibility, including donor screening and testing, are set out separately in subpart C of this part.

(b) *Core CGTP requirements*. The following are core CGTP requirements:

(1) Requirements relating to facilities in §1271.190(a) and (b);

(2) Requirements relating to environmental control in §1271.195(a);

(3) Requirements relating to equipment in §1271.200(a);

(4) Requirements relating to supplies and reagents in §1271.210(a) and (b);

(5) Requirements relating to recovery in §1271.215;

(6) Requirements relating to processing and process controls in §1271.220;

(7) Requirements relating to labeling controls in §1271.250(a) and (b);

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(8) Requirements relating to storage in §1271.260 (a) through (d);

(9) Requirements relating to receipt, predistribution shipment, and distribution of an HCT/P in §1271.265(a) through (d); and

(10) Requirements relating to donor eligibility determinations, donor screening, and donor testing in §§1271.50, 1271.75, 1271.80, and 1271.85.

. . . .

§ 1271.155. Exemptions and alternatives

(a) *General*. You may request an exemption from or alternative to any requirement in subpart C or D of this part.

(b) *Request for exemption or alternative*. Submit your request under this section to the Director of the appropriate Center (the Director), e.g., the Center for Biologics Evaluation and Research or the Center for Devices and Radiological Health. The request must be accompanied by supporting documentation, including all relevant valid scientific data, and must contain either:

(1) Information justifying the requested exemption from the requirement, or

(2) A description of a proposed alternative method of meeting the requirement.

. . . .

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U.S. CONSTITUTION

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Article I, Section 8, Clause 3

The Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes. . . .

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Article VI, Section 2

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

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Amendment I

Ratified Dec. 15, 1791.

Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances.

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Amendment V

Ratified Dec. 15, 1791.

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

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Amendment IX

Ratified Dec. 15, 1791.

The enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people.

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Amendment X

Ratified Dec. 15, 1791.

The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

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Amendment XIV

Passed by Congress June 13, 1866. Ratified July 9, 1868.

Section 1.

All persons born or naturalized in the United States, and subject to the jurisdiction thereof, are citizens of the United States and of the State wherein they reside. No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

. . . .

Section 5.

The Congress shall have the power to enforce, by appropriate legislation, the provisions of this article.

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Amendment XVIII

Passed by Congress December 18, 1917. Ratified January 16, 1919. Repealed by amendment 21.

Section 1.

After one year from the ratification of this article the manufacture, sale, or transportation of intoxicating liquors within, the importation thereof into, or the exportation thereof from the United States and all territory subject to the jurisdiction thereof for beverage purposes is hereby prohibited.

Section 2.

The Congress and the several States shall have concurrent power to enforce this article by appropriate legislation.

Section 3.

This article shall be inoperative unless it shall have been ratified as an amendment to the Constitution by the legislatures of the several States, as provided in the Constitution, within seven years from the date of the submission hereof to the States by the Congress.

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Amendment XXI

Passed by Congress February 20, 1933. Ratified December 5, 1933.

Section 1.

The eighteenth article of amendment to the Constitution of the United States is hereby repealed.

Section 2.

The transportation or importation into any State, Territory, or possession of the United States for delivery or use therein of intoxicating liquors, in violation of the laws thereof, is hereby prohibited.

Section 3.

This article shall be inoperative unless it shall have been ratified as an amendment to the Constitution by conventions in the several States, as provided in the Constitution, within seven years from the date of the submission hereof to the States by the Congress.

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APPENDIX: CHAPTER GUIDES

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How To Use These Chapter Guides

Students: These Chapter Guides are designed to make it easier for you to locate the statutory and regulatory reading assigned in the companion casebook, *Food and Drug Regulation: A Statutory Approach* (2021). The first column ("CB Page #") lists the page of the casebook on which each reading is assigned. The second-to-last column ("2024 Supp. Page #) lists the page of this Supplement on which the assigned material begins. The final column is for you to use to check off each reading assignment as you complete it.

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Chapter Guide: Casebook Chapter 1

Chapter 1: Agency Structure and Product Categories						
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9	PHSA	351	Regulations of biological products	*Subsection (i) only*	355, 356	
9	21 C.F.R.	3.2	[regulatory definition of combination products]		371	
9	21 C.F.R.	1271.3(d)	[definition of "Human cells, tissues, and cellular or tissue based products" (HCT/Ps)]		476	
9	FFDCA	301	Prohibited acts	*Subsections (a), (b), and (c) only*	104	
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111	FFDCA	911	Modified risk tobacco products		302	
113	FFDCA	905	Annual registration	*Subsection (j) only*	290, 291	

* This is incorrectly listed as "FFDCA § 505H" on page 104 of the casebook. That casebook page should instead have referred to "FFDCA § 505G."

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113	FFDCA	910	Application for review of certain tobacco products	*Subsection (a)(3) only*	298	
118	FFDCA	506	Expedited approval of drugs for serious or life threatening diseases or conditions	*Subsection (a) and (b) only*	178, 179	
118	FFDA	515B*	Breakthrough devices		210	
119	FFDCA	506	Expedited approval of drugs for serious or life threatening diseases or conditions	*Subsection (g) only*	178, 181	
125	FFDCA	409	Food additives	*Subsection (j) only*	135, 137	
125	FFDCA	505	New drugs	*Subsection (i) only*	161, 164	
125	FFDCA	512	New animal drugs	*Subsections (a)(3) and (j) only***	191, 195	
126	FFDCA	520	General provisions respecting control of devices for human use	*Subsection (g) only*	213, 214	
126	FFDCA	721	Color additives	*Subsection (f) only*	264, 268	
126	FFDCA	910	Application for review of certain tobacco products	*Subsection (g) only*	298, 301	
131	FFDCA	561	Expanded access to unapproved therapies and diagnostics		221	
134	FFDCA	564	Authorization for medical products for use in emergencies		224	
134	FFDCA	564A	Emergency use of medical products		227	
134	FFDCA	564B	Products held for emergency use		229	

* This is incorrectly listed as "FFDCA § 515C" on page 118 of the casebook. That casebook page should instead have referred to "FFDCA § 515B."

** The casebook asks you to read only subsection (a)(3) of this section. However, it should have also asked you to read subsection (j) as well, so that subsection is included here.

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Chapter Guide: Casebook Chapter 5

Chapter 5: Background Requirements						
CB Page #	**Statute Name or U.S.C./ C.F.R. Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
142	FFDCA	402	Adulterated food	*Subsections (a) and (f) only*	122, 123	
142	FFDCA	406	Tolerances for poisonous or deleterious substances in food regulations		133	
142	FFDCA	418	Hazard analysis and risk-based preventative controls		143	
142	FFDCA	501	Adulterated drugs and devices	*Subsections (a), (h) and (j) only*	147, 149	
142	FFDCA	601	Adulterated cosmetics		238	
142	FFDCA	902	Adulterated tobacco products		287	
142	PHSA	361	Regulations to control communicable diseases	*Subsection (a) only*	362	
152	FFDCA	201	Definitions; generally.	*Subsections (k), (l) and (m) only*	94, 95, 96	
152	FFDCA	301	Prohibited acts	*Subsection (k) only*	104, 105	
152	FFDCA	403	Misbranded food		125	
152	FFDCA	502	Misbranded drugs and devices		150	
152	FFDCA	602	Misbranded cosmetics		239	
152	FFDCA	903	Misbranded tobacco products		288	
155	FFDCA	415	Registration of food facilities		141	
155	FFDCA	510	Registration of producers of drugs and devices	*Subsections (a)–(j) only*	185, 187	

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155	FFDCA	905	Annual registration	*Subsections (a)–(i) only*	290,291	

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Chapter Guide: Casebook Chapter 6

Chapter 6: Food						
CB Page #	**Statute Name or U.S.C./ C.F.R. Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
167	FFDCA	201	Definitions; generally,	*Subsection (f) only*	94	
170	FFDCA	402	Adulterated food		122	
171	FFDCA	403	Misbranded food		125	
176	FFDCA	401	Definitions and standards for food		121	
176	FFDCA	403	Misbranded food	*Subsection (c) only*	125	
176	21 C.F.R.	101	Food labeling	*Subsections 101.1,101.2,101.4,101.9, and 101.18 only*	396, 397, 404	
176	21 C.F.R.	102	Common or usual name for nonstandardized foods		407	
187	21 U.S.C.	451	Congressional statement of findings		333	
187	21 U.S.C.	452	Congressional declaration of policy		334	
187	21 U.S.C.	458	Prohibited acts		336	
187	21 U.S.C.	601	Definitions		337	
187	21 U.S.C.	602	Congressional statement of findings		340	
187	21 U.S.C.	603	Examination of animal prior to slaughter; use of humane methods		341	
187	21 U.S.C.	604	Post mortem examination of carcasses and marking or labeling; destruction of carcasses condemned; reinspection		342	

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187	21 U.S.C.	610	Prohibited acts		343	
187	21 U.S.C.	661	Federal and state cooperation		344	
187	21 U.S.C.	1031	Congressional statement of findings		345	
187	21 U.S.C.	1032	Congressional declaration of policy		346	
187	21 U.S.C.	1033	Definitions		347	
187	21 U.S.C.	1037	Prohibited acts		349	
197	U.S. Constitution	Amendment 18			492	
197	U.S. Constitution	Amendment 21			493	

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Chapter Guide: Casebook Chapter 7

Chapter 7: Food Additives						
CB Page #	**Statute Name or U.S.C./ C.F.R. Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
227	FFDCA	201	Definitions; generally	*Subsection (s) only*	94, 98	
227	FFDCA	409	Food additives		135	

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Chapter Guide: Casebook Chapter 8

Chapter 8: Dietary Supplements						
CB Page #	**Statute Name or U.S.C./ C.F.R. Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
245	FFDCA	201	Definitions; generally	*Subsections (g)(1), (s), and (ff) only*	94, 98, 100	
245	FFDCA	402	Adulterated food	*Subsections (f) and (g) only*[*]	122, 123, 124	
245	FFDCA	403	Misbranded food	*Subsections (r) and (s) only*	125, 126, 129	
245	FFDCA	403B	Dietary supplement labeling exemptions		131	
245	FFDCA	411	Vitamins and minerals		138	
245	FFDCA	413	New dietary ingredients		140	
245	21 C.F.R.	105	Foods for special dietary use		409	
245	21 C.F.R.	190	Dietary supplements		411	

[*] The casebook erroneously lists, in addition to those listed here, subsections (r) and (s). No such subsections exist for FFDCA § 402, and these are accordingly omitted here.

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Chapter Guide: Casebook Chapter 9

Chapter 9: Label Claims for Food and Dietary Supplements						
CB Page #	**Statute Name or U.S.C./ C.F.R. Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
271	FFDCA	201	Definitions; generally	*Subsections (g)(1) and (ff) only*	94, 100	
271	FFDCA	403	Misbranded food	*Subsection (r) only*	125, 126	
271	21 C.F.R.	101.13	Nutrient claims—general principles		399	
271	21 C.F.R.	101.14	Health claims: general requirements		400	
271	21 C.F.R.	101.93	Certain types of statements for dietary supplements		404	

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Chapter Guide: Casebook Chapter 10

Chapter 10: Drugs						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
305	FFDCA	201	Definitions; generally	*Subsections (g)(1) and (p) only*	94, 96	
305	FFDCA	501	Adulterated drugs and devices	*Subsections (a)–(d) only*	147, 148	
305	FFDCA	502	Misbranded drugs and devices	*Subsections (a)–(c), (f), and (o) only*	150, 151, 153	
305	PHSA	351	Regulation of biological products	*Subsection (j) only*	355, 357	
324	21 C.F.R.	310.6	Applicability of "new drug" or safety or effectiveness findings in drug efficacy study implementation notices and notices of opportunity for hearing to identical, related, and similar drug products		413	
324	21 C.F.R.	310.100	New drug status opinions; statement of policy		413	
324	21 C.F.R.	314.126	Adequate and well-controlled studies		417	

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Chapter Guide: Casebook Chapter 11

Chapter 11: Animal Drugs						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
395	FFDCA	201	Definitions	*Subsections (g)(1) and (v) only*	94, 99	
395	FFDCA	501	Adulterated drugs and devices	*Subsections (a)(5) and (a)(6) only*	147	
395	FFDCA	502	Misbranded drugs and devices	*Subsection (w) only*	150, 154	
395	FFDCA	512	New animal drugs		191	
401	21 U.S.C.	151	Preparation and sale of worthless or harmful products for domestic animals prohibited; preparation to be in compliance with rules at licensed establishments		329	
401	21 U.S.C.	152	Importation regulated and prohibited		330	
401	21 U.S.C.	153	Inspection of imports; denial of entry and destruction		331	
401	21 U.S.C.	154	Regulations for preparation and sale; licenses		332	
401	9 C.F.R.	101	Definitions		367	
401	9 C.F.R.	102	Licenses for biological products		369	

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Chapter Guide: Casebook Chapter 12

Chapter 12: Medical Devices						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
407	FFDCA	201	Definitions; generally	*Subsection (h) only*	94, 95	
407	FFDCA	501	Adulterated drugs and devices	*Subsections (f), (g), (h), (i) and (j) only*	147, 148, 149	
407	FFDCA	502	Misbranded drugs and devices	*Subsections (a), (b), (c), (e), (f), (j), (o), (q), and (r) only*	150, 151, 152, 153	
407	FFDCA	520	General provisions respecting control of devices intended for human use		213	
407	21 C.F.R.	868	Anesthesiology devices		459	
407	21 C.F.R.	870	Cardiology devices		460	
407	21 C.F.R.	872	Dental devices		461	
407	21 C.F.R.	878	General and plastic surgery devices		462	
407	21 C.F.R.	880	General hospital and personal use devices		464	
407	21 C.F.R.	890	Physical medicine devices		465	
407	21 C.F.R.	892	Radiology devices		466	
407	21 C.F.R.	895	Banned devices		467	
407	21 C.F.R.	898	Performance standard for electrode lead wires and patient cables		469	
413	FFDCA	510	Registration of producers of drugs and devices	*Subsections (k), (l), (m), and (n) only*	185, 188, 189, 190	

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413	FFDCA	513	Classification of devices intended for human use		197	
413	FFDCA	515	Premarket approval		205	
413	21 C.F.R.	807	Establishment registration and device listing for manufacturers and initial importers of devices		444	
413	21 C.F.R.	814	Premarket approval of medicl devices		454	
413	21 C.F.R.	860	Medical device classification procedures		455	

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Chapter Guide: Casebook Chapter 13

Chapter 13: Combination Products						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
439	FFDCA	503	Exemptions and considerations for certain drugs, devices, and biological products	*Subsection (g) only*	155, 156	
439	FFDCA	201	Definitions, generally	*Subsection (rr) only*	94, 103	
439	21 C.F.R.	3	Product jurisdiction		371	
439	21 C.F.R.	4	Regulation of combination products		374	

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Chapter Guide: Casebook Chapter 14

Chapter 14: Biologics						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
455	PHSA	351	Regulation of biological products		355	
455	PHSA	361	Regulations to control communicable disease		362	
455	21 C.F.R.	600	General		429	

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Chapter Guide: Casebook Chapter 15

Chapter 15: Human Cells, Tissues, and Cellular and Tissue-Based Products						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
475	PHSA	361	Regulations to control communicable diseases		362	
475	21 C.F.R.	1270	Human tissue intended for transplantation		474	
475	21 C.F.R.	1271	Human cells, tissues, and cellular and tissue-based products		476	

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Chapter Guide: Casebook Chapter 16

Chapter 16: Cosmetics						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
495	FFDCA	201	Definitions; generally	*Subsection (i) only*	94, 95	
495	FFDCA	601	Adulterated cosmetics		238	
495	FFDCA	602	Misbranded cosmetics		239	
495	FFDCA	603	Regulation making exemptions		240	
495	15 U.S.C.	1452	Unfair and deceptive packaging and labeling; scope of prohibition	*Subsection (a) only*[*]	322	
495	15 U.S.C.	1454	Rules and regulations	*Subsection (a) only*	323	
495	15 U.S.C.	1456	Enforcement	*Subsection (a) only*	324	
495	15 U.S.C.	1459	Definitions	*Subsection (a) only*	325	
495	21 C.F.R.	700	General		435	
495	21 C.F.R.	710	Voluntary registration of cosmetic product establishments		439	
495	21 C.F.R.	720	Voluntary filing of cosmetic product ingredient composition statements		440	
495	21 C.F.R.	740	Cosmetic product warning statements		442	

[*] The casebook erroneously lists subsection (i) here. No such subsection exists for 15 U.S.C. § 1452, and subsection (a) is accordingly substituted here.

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Chapter Guide: Casebook Chapter 17

Chapter 17: Color Additives						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
507	FFDCA	201	Definitions; generally	*Subsection (t) only*	94, 98	
507	FFDCA	721	Color additives		264	
507	21 C.F.R.	70	Color additives		390	
507	21 C.F.R.	71	Color additive petitions		394	

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Chapter Guide: Casebook Chapter 18

Chapter 18: Tobacco Products						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
547	FFDCA	201	Definitions; generally	*Subsection (rr) only*	94, 103	
547	FFDCA	900	Definitions	*Subsections (1)–(4), (11)–(12), (15), and (17)–(18)*	282, 283	
547	FFDCA	901	FDA authority over tobacco products		285	
547	FFDCA	902	Adulterated tobacco products		287	
547	FFDCA	903	Misbranded tobacco products		288	
547	21 C.F.R.	1100	Tobacco products subject to FDA authority		470	
547	21 C.F.R.	1140	Cigarettes, smokeless tobacco, and covered tobacco products		472	

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Chapter Guide: Casebook Chapter 19

Chapter 19: FDA Enforcement						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
574	FFDCA	301	Prohibited acts	*Please skim full section, but do not get bogged down in the details. The idea is to get an idea of the broad range of actions prohibited.*	104	
574	FFDCA	302	Injunction proceedings		111	
574	FFDCA	303	Penalties	*Subsections (a), (c)(1), and (c)(2) only*	112	
574	18 U.S.C.	3571	Sentence of fine		327	
574	FFDCA	304	Seizure	*Subsections (a)(1), (b), (g)(1), and (h)(1) only*	113, 114	
575	FFDCA	305	Hearing before report of criminal violation		116	
575	FFDCA	306	Debarment, temporary denial of approval, and suspension	*Subsections (a), (b)(1), (c)(1), and (e) only*	117	
575	FFDCA	307	Civil penalties	*Subsection (a) only*	118	
575	FFDCA	309	Report of minor violations		119	
576	FFDCA	702	Examinations and investigations	*Subsections (a)(1) and (e) only*	258	
576	FFDCA	703	Records		259	
576	FFDCA	704	Inspection		260	
576	FFDCA	705	Publicity		262	
576	FFDCA	709	Presumption of existence of jurisdiction		263	

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Chapter Guide: Casebook Chapter 20

Chapter 20: Federal Preemption						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
603	U.S. Constitution	Article VI, Section 2			486	
603	FFDCA	521	State and local requirements respecting devices		220	
603	21 C.F.R.	808	Exemptions from federal preemption of state and local medical device requirements		450	
603	21 C.F.R.	314.70	Supplements and other changes to an approved NDA		415	

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Chapter Guide: Casebook Chapter 21

Chapter 21: Regulation of Imports						
CB Page #	**Statute Name or U.S.C./ C.F.R Title**	**§**	**Section Title**	**Sections Assigned**	**2024 Supp. Page #**	✓
658	FFDCA	311	Extraterritorial jurisdiction		120	
658	FFDCA	801	Imports and exports	*Subsection (a) only*	269	
658	FFDCA	803	Office of international relations		271	
658	FFDCA	804	Importation of prescription drugs	*Subsections (b) and (j) only*	272, 273	
658	FFDCA	805	Foreign supplier verification program		275	
658	FFDCA	806	Voluntary qualified importer program	*Subsection (a) only*	277	
658	FFDCA	807	Inspection of foreign food facilities		278	
658	FFDCA	808	Accreditation of third-party auditors	*Subsection (a) only*	279	
658	FFDCA	809	Recognition of foreign government inspections		281	

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