Food and Drug Regulation

Food and Drug Regulation: A Statutory Approach

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To my parents

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Acknowlegments

This project developed over many years, and I accordingly owe many thanks. The first set goes to the students who have taken my food and drug classes over the years. From them, I learned the importance of organizing course materials in an approachable manner—something I hope I have managed to do here.

I am grateful for many years of summer research funding from Penn State Law, which allowed the project to develop in response to each year's class. A Fall 2019 sabbatical provided by Penn State University gave me time to restructure the book in a manner that, I hope, makes it more useful to the reader.

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Preface — About This Book

This book is intended for a law school survey course on food and drug regulation. It covers the Food and Drug Administration's (FDA's) regulation of food, food additives, dietary supplements, drugs, animal drugs, medical devices, combination products, biologics, HCT/Ps (human cells, tissues, and cellular and tissue-based products), cosmetics, color additives, and tobacco products. It also covers administrative procedure, regulation of research, FDA enforcement, federal preemption, and regulation of imports. It presents more limited material on related areas regulated primarily by other agencies.[1] In addition to covering this substantive material, the book will introduce you to the process of understanding a complex statute, its implementing regulations, and related enforcement policies.

The book's coverage is not intended to be comprehensive. Several existing books present treatise-level coverage and even those cannot cover FDA's regulatory programs comprehensively. This book instead focuses on core aspects of selected FDA regulatory programs in the areas of food and medical products.[2]

Food and drug regulation is primarily a statutory and regulatory subject. Accordingly, this book relies on a different set of documents and a different style of presentation than a typical casebook. The book emphasizes guided reading of the Federal Food, Drug, and Cosmetic Act, related statutes, FDA regulations, and Federal Register documents. Cases are presented primarily when they involve major issues of statutory interpretation, are historically significant, or are in one of the areas — such as federal preemption — where case law plays a major role in the overall regulatory scheme. Cases are also included where they provide a concise discussion of a regulatory program or a useful illustration of a concept.

This book is designed to work as a set with the accompanying Statutory & Regulatory Supplement (Supplement). The Supplement is available free, in PDF format, on this book's page of the Carolina Academic Press website.[3] The statutes and regulations in the Supplement have been aggressively edited, like the cases in a typical

1. These include USDA-regulated foods (meat, eggs, poultry, and fish of the order siluriformes (catfish and related species)), agricultural biotechnology, alcohol, controlled substances, and veterinary biologics.

2. The main categories the book does not address are animal food and feed, radiation-emitting products, and medical gases.

3. *See* https://cap-press.com/books/isbn/9781531004453/Food-and-Drug-Regulation.

law school casebook, to emphasize those aspects that are most important to a general understanding of the subject.

Structure of the Book

The book is organized around the structure of the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) and the relevant portion of the Public Health Services Act (PHSA).[4] This means that Chapter IV products (food, food additives, and dietary supplements), Chapter V products (drugs, animal drugs, medical devices, and combination products), and PHSA products (biologics and HCT/Ps) are each grouped together. The single-product-category chapters — Chapter VI (cosmetics), Chapter VII (color additives), and Chapter IX (tobacco products) — are then included in a final, catch-all group. Parts I, II, and VII of the book address cross-cutting issues, while Parts III, IV, V, and VI address the four groups of individual product categories. Part VIII contains the appendices.

Part I of the book introduces the basic structure of FDA and the FFDCA. Within Part I, Chapter 1 addresses the structure of the agency and the product categories set out in the FFDCA. Chapter 2 addresses administrative procedure. It contains material on administrative procedure generally and on administrative procedure specific to FDA.

Part II of the book addresses regulation of research, marketing authorization, and background regulatory requirements associated with marketing authorization. This Part emphasizes those aspects of research, marketing authorization, and background requirements that are similar across multiple product categories. Within Part II, Chapter 3 addresses regulation of research. It focuses on FDA regulation of human-subject research. Chapter 4 addresses marketing authorization. It contains material on pathways to market, designations, and access before market authorization. Chapter 5 addresses background requirements associated with marketing authorization. It contains information on production-process requirements, labeling requirements, establishment registration requirements, user fees, and postmarket requirements.

Part III of the book addresses those products regulated primarily under Chapter IV of the FFDCA. Chapter 6 addresses food, Chapter 7 addresses food additives, and Chapter 8 addresses dietary supplements. Chapter 9 does not address a single product category. Instead, it contains material on label claims for the two Chapter IV categories — food and dietary supplements — for which label-claim

4. Please note that this book uses: Roman numerals when referring to *parts of this book* (Part V); Arabic numerals when referring to *parts of the CFR* (21 C.F.R. Part 5); Arabic numerals when referring to *chapters of this book* (Chapter 5); and roman numerals when referring to *chapters of the FFDCA* (Chapter V).

issues arise. Label claims receive a separate chapter to avoid presenting duplicative material in the earlier chapters on food and dietary supplements.

Part IV of the book addresses those products regulated primarily under Chapter V of the FFDCA. Chapter 10 addresses drugs, Chapter 11 addresses animal drugs, Chapter 12 addresses medical devices, and Chapter 13 addresses combination products.

Part V of the book addresses those products regulated primarily under the PHSA. Chapter 14 addresses those aspects of biological products regulated primarily by the PHSA.[5] Chapter 15 addresses HCT/Ps.

Part VI of the book addresses those products regulated under the FFDCA Chapters VI, VII, and IX. Chapter 16 addresses cosmetics, Chapter 17 addresses color additives, and Chapter 18 addresses tobacco products.

Part VII returns to cross-cutting issues of the type addressed in Parts I and II. Chapter 19 addresses FDA enforcement, Chapter 20 addresses federal preemption, and Chapter 21 addresses regulation of imports.

Part VIII is an appendix recommending further reading. Its focus is on books rather than academic articles, with a particular emphasis on items available as audiobooks (a wonderful help to the busy lawyer during commuting or exercise). It includes both law-specific reading and material on scientific, technological, and industrial developments relevant to food and drug regulation.

For a description of the structure of individual chapters, see "Introduction to this Book" in Chapter 1, Part A.

Citation Format and Editorial Approach

I have aggressively edited the documents that I have excerpted in this book. My goal in doing this is to emphasize those aspects of the excerpted documents that are most relevant to basic goal of this book: presenting an approachable overview of the basic structure of food and drug regulation.

Citations in this book conform generally to the 20th edition of *The Bluebook: A Uniform System of Citation*. Significant exceptions are the following:

I have cited Federal Register documents in a format that emphasizes the date of publication and type of document, rather than document title. I have done this for two reasons. First, these documents frequently contain cumbersome multipart titles that — despite their length — are of only limited value in describing the document's

5. As you will see later, all products meeting the statutory definition of biological product, PHSA §351(i)(1), also meet the statutory definition of drug, FFDCA §201(g)(1). Accordingly, much of this chapter of the book is focused on the relationship between FDA's biologics division (transferred from the National Institute of Health to FDA in the 1970s) and FDA's drugs division.

content. Second, the administrative rulemaking process typically results in multiple documents with very similar titles. This book uses the format below, which I believe will help you distinguish more clearly between the different documents cited:

> *[date of publication in YYYY-MM-DD format] [abbreviated agency name (FDA, USDA, EPA, etc.)] [type of document (notice, proposed rule, final rule, etc.)], [title or shortened title] [FR volume #]* Fed. Reg. *[FR page #]*

Within quoted original sources, the original citation format is retained except where I have determined that a modification will increase clarity or make the document more readable.

Also within quoted original sources, I have made the following omissions without any indication in the text:

- omitted most citations and footnotes, retaining only those that I believe will be of use to the reader (retained footnotes have their original numbering);
- omitted most quotation marks in situations where courts are simply quoting the language of prior judicial opinions as part of their own sentences (in the standard style of judicial opinion-writing);[6]
- modified the format of some retained citations to conform to the style of this book;
- replaced the use of a series of asterisks (common in older documents) with the modern use of three-dot or four-dot ellipses, as appropriate;
- omitted text from the part of an excerpted document that precedes the quoted language.

Where I have omitted text from a quoted source, I have used three-dot ellipses to indicate omissions of less than a sentence and four-dot ellipses to indicate omissions of a full sentence or more.

Within quotations and excerpts referencing the FFDCA or the PHSA, I have replaced references to U.S. Code section numbers with references to the corresponding FFDCA section numbers, following the standard approach in this book. Where I have done this, I have used the notation "[FFDCA §]" to indicate the change.

One final editorial convention bears emphasis. Both the FFDCA and the PHSA are phrased in terms of authorities granted to, and obligations imposed upon, "the Secretary" — meaning the Secretary of Health and Human Services — rather than FDA. See FFDCA §201(d). The Secretary of Health and Human Services, however, has delegated nearly all of the authority to administer these statutes to the Commissioner of Food and Drugs. See FDA Staff Manual Guides, Volume

6. This is necessary to facilitate omission of citations to the quoted documents, with the aim of making those excerpts more readable. I have done this only in excerpts, not within the text of the book. Even within excerpts, I have never intentionally omitted quotation marks from sources other than judicial opinions.

II — Delegations of Authority § 1410.10 (Effective Date: August 26, 2016). To make textual descriptions of statutory language more readable, I have generally substituted "FDA" for "the Secretary" in describing the language of the statute. This means that:

- In places where the FFDCA grants "the Secretary" authority to take a particular action, I typically describe it as granting "FDA" such authority.
- In places where the FFDCA requires "the Secretary" to take some action, I typically describe it as requiring "FDA" to take such action.