Law, Regulation, Guidances, and Administrative Procedures

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Outline

- Resources
- Law – Food, Drug, and Cosmetic Act
  - ✓Judicial Deference
- Regulation – Code of Federal Regulations
- Policy – Guidance
- Administrative Procedures

Resources

- FDA Law, Regulation, and Policy
- Judicial Deference to Agency Action, Engage Vol. 9, Issue 3
- CRS Report – A Brief Overview of Rulemaking and Judicial Review

Law – Federal Food, Drug, and Cosmetic Act

- See https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act

Laws Enforced by FDA

The Food and Drugs Act of 1906 was the first of more than 200 laws that constitute one of the world's most comprehensive and effective networks of public health and consumer protections. Here are a few of the congressional milestones:

- The Federal Food, Drug, and Cosmetic Act of 1938 was passed after a legally marketed toxic elixir killed 107 people, including many children. The FD&C Act completely overhauled the public health system. Among other provisions, the law authorized the FDA to demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections.
- The Kefauver-Harris Amendments of 1962, which were inspired by the thalidomide tragedy in Europe (and the FDA's vigilance that prevented the drug's marketing in the United States), strengthened the rules for drug safety and required manufacturers to prove their drugs' effectiveness.
- The Medical Device Amendments of 1976 followed a U.S. Senate finding that faulty medical devices had caused 10,000 injuries, including 731 deaths. The law applied safety and effectiveness safeguards to new devices.

Today, the FDA regulates $1 trillion worth of products a year. It ensures the safety of all food except for meat, poultry and some egg products; ensures the safety and effectiveness of all drugs, biological products (including blood, vaccines and tissues for transplantation), medical devices, and animal drugs and feed; and makes sure that cosmetics and medical and consumer products that emit radiation do no harm.

Law – Federal Food, Drug, and Cosmetic Act

- See https://www.fda.gov/regulatory-information/laws-enforced-fda/selected-amendments-fdc-act

Selected Amendments to the FD&C Act

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Selected Amendments to the FD&C Act

- 21st Century Cures Act
- FDA Reauthorization Act of 2017 (FDARA)
- Food and Drug Administration Amendments Act (FDAAA) of 2007
- Food and Drug Administration Modernization Act (FDAMA) of 1997
- Food and Drug Administration Safety and Innovation Act (FDASIA)
- Prescription Drug Marketing Act of 1987

To find these Public Laws, go to https://congress.gov/ and click on Public Laws.

Selected Amendments to the Federal Food, Drug and Cosmetic Act

- Infant Formula Act of 1980
  Public Law (PL) 96-359 (Oct. 26, 1980)
- Orphan Drug Act
  PL 97-414 (Jan. 4, 1983)
- Drug Price Competition and Patent Term Restoration Act of 1984
  PL 98-417 (Sep. 24, 1984)
- Prescription Drug Marketing Act of 1987
  PL 100-293 (Apr. 22, 1988)
- Generic Animal Drug and Patent Term Restoration Act of 1988
  PL 100-670 (Nov. 16, 1988)
- Nutrition Labeling and Education Act of 1990
  PL 101-535 (Nov. 8, 1990)
- Safe Medical Devices Act of 1990
  PL 101-629 (Nov. 28, 1990)
- Medical Device Amendments of 1992
  PL 102-300 (June 16, 1992)
- Prescription Drug Amendments of 1992; Prescription Drug User Fee Act of 1992
  PL 102-571 (Oct. 29, 1992)
- Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994
  PL 103-396 (Oct. 22, 1994)
- Dietary Supplement Health and Education Act of 1994
  PL 103-417 (Oct. 25, 1994)
- FDA Export Reform and Enhancement Act of 1996
  PL 104-134 (April 26, 1996)

Law – Federal Food, Drug, and Cosmetic Act

- See https://www.fda.gov/regulatory-information/laws-enforced-fda/selected-amendments-fdc-act

Federal Food, Drug, and Cosmetic Act (FD&C Act)

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FD&C Act Reference Information

United States Code, Title 21

The laws of the United States are organized by subject into the United States Code. The United States Code contains only the currently enacted statutory language. The official United States Code is maintained by the Office of the Law Revision Counsel in the United States House of Representatives. The Office of the Law Revision Counsel reviews enacted laws and determines where the statutory language should be codified related to its topic. The Federal Food, Drug, and Cosmetic Act and subsequent amending statutes are codified into Title 21 Chapter 9 of the United States Code.

The listing of FD&C Act sections presented here identifies both the FD&C Act and U.S. Code section numbers, which can be used to narrow your search on the Law Revision Counsel website.

To search the FD&C Act on the Law Revision Counsel website, use the Advanced Search to limit the your search to Title 21.

To search the FD&C Act on the Law Revision Counsel website, you may either search by U.S. code section number or browse the Title 21 section listing.

Law – Federal Food, Drug, and Cosmetic Act (cont'd)

- Judicial Deference – how judiciary interprets statutes and administrative actions
  - ✓ Administrative agencies – delegated authority and expertise
  - ✓ Deference rule – courts defer to reasonable interpretation by administrative agency

Regulation – CFR

- Code of Federal Regulations (CFR), 21 CFR 10.40
- Administrative Procedures Act (APA) – prescribes procedures for agency actions i.e., rulemaking, and sets standards for judicial review (arbitrary and capricious standard)
  - ✓ Informal/Notice and Comment
    - Notice of proposed rulemaking
    - Comment period
    - Final Rule
  - ✓ Formal
  - ✓ Hybrid
  - ✓ Direct Final
  - ✓ Negotiated

Regulation – CFR

- See https://www.ecfr.gov/

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Title	Volume	Chapter	Browse Parts	Regulatory Entity
Title 21 Food and Drugs	1	I	1-99	FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES
	2		100-169	
	3		170-199	
	4		200-299	
	5		300-499	
	6		500-599	
	7		600-799	
	8		800-1299	
	9	II	1300-1399	DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE
		III	1400-1499	OFFICE OF NATIONAL DRUG CONTROL POLICY

Need assistance?

Regulation – FR Notices

- See https://www.fda.gov/regulatory-information/dockets-management/federal-register-fr-notices

Federal Register (FR) Notices

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In order to align with federal government and FDA goals of eliminating duplication of information and effort, the Division of Dockets Management (DDM) does not post *Federal Register* documents on the FDA.gov website. Use the following links to find FDA *Federal Register* documents in the U.S. Government Printing Office Federal Digital System and the Office of the Federal Register website.

Advance Display:

- Office of the Federal Register Electronic Public Inspection Desk
- Office of the Federal Register enhanced public inspection website

Today's Federal Register:

- Today's Federal Register Table of Contents

Historical to Present Federal Register documents:

- GPO Federal Register Database (1994 to present)
- HeinOnline disclaimer icon provides online access to Federal Registers from 1936-forward

Using the Regulations.gov Website

For instructions about how to search for FDA Federal Register documents, dockets, and daily listings of documents posted on Regulations.gov; and how to submit electronic comments:

- Instructions for Using Regulations.gov

Tools and Resources

- Regulations.gov
- Instructions for Using Regulations.gov
- Electronic Code of Federal Regulations (GPO)

Policy – Guidances

- Section 701(h) FDCA, Good Guidance Practices – 21 CFR 10.115
- Overview:
  - ✓ Guidance documents explain the agency's interpretation of, or policy on, a regulatory issue
  - ✓ Does not create or confer any rights for or on any person and do not operate to bind FDA or the public
  - ✓ Alternative approach can be used if the approach satisfies the requirements of the applicable statutes and regulations
- Although guidance documents are not binding on FDA, FDA employees must not deviate from guidances without appropriate justification and supervisory concurrence, section 701(h) FDCA
- Types:
  - ✓ Level 1 Guidance – set forth the agency's initial interpretations of new significant regulatory requirements; describe substantial changes in FDA's earlier interpretation or policy; and deal with complex scientific or highly controversial issues
  - ✓ Level 2 Guidance – usually address existing practices or minor changes in FDA's interpretation or policy

Policy – Guidances (cont'd)

- See https://www.fda.gov/regulatory-information/search-fda-guidance-documents

Search for FDA Guidance Documents

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Search for FDA Guidance Documents

- Search General and Cross-Cutting Topics Guidance Documents
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- Clinical Trials Guidance Documents
- Combination Products Guidance Documents
- Import and Export Guidance Documents
- Cross-cutting Guidance Documents

The table below lists all official FDA Guidance Documents and other regulatory guidance. You can search for documents using key words, and you can narrow or filter your results by product, date issued, FDA organizational unit, type of document, subject, draft or final status, and comment period.

This feature is provided to give a convenient way to search for all FDA guidance documents from a single location.

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About FDA Guidance Documents

Commenting on Guidance Documents

Report on Good Guidance Practices

Administrative Procedures

- Petitions, 21 CFR Part 10
- Citizen Petitions, 21 CFR 10.30
  - ✓ Any "interested person" can petition Commissioner to:
    - Issue, amend or revoke a regulation
    - Issue, amend or revoke an order
    - Take or refrain from taking any other form of administrative action
- Petition for Reconsideration, 21 CFR 10.33
  - ✓ Any "interested person" may ask FDA to reconsider a decision on a citizen petition
- Petition for Stay of Action, 21 CFR 10.35
  - ✓ Any "interested person" may ask FDA to stay the effective date of any administrative action for a specific or indefinite period of time
- Judicial Review of Final Action on a Petition

Administrative Procedures

- Hearings
- Formal Evidentiary Public Hearing, 21 CFR Part 12
  - ✓ Where FDA proposes to deny or revoke the approval to market a medical product or on any matter when "it would be in the public interest to do so"
- Hearing Before A Public Board of Inquiry, 21 CFR Part 13
  - ✓ For situations involving complex scientific and medical issues
- Public Hearing Before a Public Advisory Committee, 21 CFR Part 14
  - ✓ Advisory committees provide FDA advice on both policy matters and on specific technical or scientific issues, which might relate to pending regulatory decisions
- Public Hearing Before the FDA Commissioner, 21 CFR Part 15
  - ✓ Used when required under specific statutory or regulatory provisions, or at the Agency's discretion on complex or controversial regulatory matters
- Regulatory Hearings, 21 CFR Part 16
  - ✓ called at discretion of Commissioner when considering regulatory action, or when provided by law or regulation