*This is your Release #6 (February 2023)*

# FDA Deskbook

## *A Compliance and Enforcement Guide*

**Edited by**
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**& Anne K. Walsh**

This sixth release to *FDA Deskbook: A Compliance and Enforcement Guide* continues to assist stakeholders navigate the labyrinth requirements of the Federal Food, Drug, and Cosmetic Act and updates the treatise with the most current legal, regulatory, and compliance requirements and developments. Highlights of Release #6 include:

**Chapter 1, FDA Administrative Actions**. Reviews Remote Regulatory Assessments (RRAs), a new activity implemented during the COVID-19 pandemic when FDA was unable to travel and conduct traditional on-site inspections. RRAs facilitate FDA's ability to provide oversight over FDA-regulated products and establishments (see section 1:4.1).

**Chapter 2, FDA Civil Enforcement Actions**. Updates the discussion of what products can be seized (see section 2:4.3).

**Chapter 4, Other Authorities Governing FDA-Regulated Entities**. Reviews the CMS authority, granted under the Inflation Reduction Act of 2022, to negotiate the selling price of a select number of high expenditure single-source Medicare Part B and Part D drugs and biologics (see section 4:5.3[E]).

**Chapter 5, Over-the-Counter Drugs**. Outlines the June 2022 FDA-issued proposed rule addressing "Additional Conditions of Nonprescription Use" (ACNU) and several new concepts and requirements for this category of Rx-to-OTC drug (see section 5:5.6).

**Chapter 10, Devices: Recalls**. Overview of the March 2022 guidance issued by FDA regarding voluntary recalls (see section 10:2.3[A]).

**Chapter 12, Devices: *In Vitro* Diagnostic Devices**. Chapter updated to cover the latest developments affecting the different regulatory

*(continued on reverse)*

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pathways for diagnostic tests and the special considerations each poses for enforcement.

**Chapter 13, Human Food and Dietary Supplements**. Overview of the National Bioengineered Food Disclosure Standard (see section 13:3.3[B]).

**Chapter 14, Tobacco Products**. Reviews developments concerning premarket tobacco applications (see section 14:6.3[B]).

**Chapter 15, Animal Products**. Reviews the FDA's final guidance for industry, titled Guidance for Industry #256, Compounding Animal Drugs from Bulk Drug Substances, which addresses the compounding of animal drugs (see section 15:7.1).

**Chapter 16, Cosmetics**. New discussion covers laws enacted by state laws that impose specific requirements on cosmetics (see section 16:8).

**Chapter 17, Controlled Substances**. Coverage of the consolidated cases of *Ruan v. United States* and *Kahn v. United States*, the U.S. Supreme Court decision that will require that the government prove subjective intent in proving a criminal violation for prescribing controlled substances (see section 17:4.1), and reviews DEA enforcement actions, including for failure to maintain complete and accurate records (see section 17:4.2); for dispensing for non-legitimate purpose (see section 17:4.3); failure to report suspicious orders (see section 17:4.4); the National Prescription Opioid Litigation (see section 17:4.5); and state prescription opioid litigation (see section 17:4.6).

**Chapter 19, Health Care Fraud and Abuse Laws**. Reviews OIG guidance on patient assistance programs (see section 19:4.1[C][1]).

**Chapter 21, FDA Inspections**. New discussion covers the effect of the COVID-19 pandemic, and related emergency declarations, on FDA inspections, both domestically and internationally (see section 21:1.2).

**Chapter 7, Drug Compounding**; **Chapter 9, Quality System Regulation**; **Chapter 18, Promotion and Marketing of Prescription Drugs, Biologics, and Devices**; and **Chapter 20, Internal Investigations** have been updated with the latest developments. To aid in your research, the **Table of Authorities** and **Index** have also been updated.

Thank you for purchasing *FDA Deskbook: A Compliance and Enforcement Guide*. If you have questions about this product, or would like information on our other products, please contact customer service at info@pli.edu or at (800) 260-4PLI.

**FILING INSTRUCTIONS**

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