

*This is your Release #3 (November 2019)*

# **FDA Deskbook**

## ***A Compliance and Enforcement Guide***

**Edited by**  
**James P. Ellison & Anne K. Walsh**

This third release to *FDA Deskbook* 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 #3 include:

**Chapter 2, FDA Civil Enforcement Actions.** Updated to cover Department of Justice's (DOJ) December 2018 update of its *Justice Manual* to provide more flexibility and to provide more potential for companies to earn cooperation credit and to resolve cases more quickly (see section 2:3.4).

**Chapter 7, Drug Compounding.** Updated to cover the criteria FDA will consider for inclusion in 503A bulks list (see section 7:4.2[A]).

**Chapter 12, Devices: *In Vitro* Diagnostic Devices.** Updated to include the April 4, 2019 Warning Letter issued by the FDA to Inova Genomics Laboratory (Inova) relating to Inova's pharmacogenomics tests (see section 12:4.5).

**Chapter 14, Tobacco Products.** Updated discussion follows the developments surrounding the FDA's June 2011 final rules mandating color graphic warnings on cigarette packs and in cigarette advertisements (see section 14:8).

**Chapter 17, Controlled Substances.** Updated to include discussion of *In re* National Prescription Opiate Litigation, in which about 2,000 federal court cases were consolidated under one opioid multidistrict litigation (MDL) (see section 17:4.5); and an overview of the numerous actions against manufacturers, distributors, and pharmacies related to the distribution and dispensing of opioids at the state and local levels (see section 17:4.6).

**Chapters 1, 3–6, 8–11, 13, 15, and 18–22** have also been updated. To aid in your research, the **Table of Authorities** and **Index** have also been updated.

Thank you for purchasing *FDA Deskbook*. 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.

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# FILING INSTRUCTIONS

## **FDA Deskbook** *A Compliance and Enforcement Guide*

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**REMOVE OLD PAGES**  
**NUMBERED:**

- Title page to 15-31
- 17-1 to I-82

**INSERT NEW PAGES**  
**NUMBERED:**

- Title page to 15-31
- 17-1 to I-83

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