



FDA Deskbook: A Compliance and Enforcement Guide

James P. Ellison, Anne K. Walsh

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FDA Deskbook: A Compliance and Enforcement Guide provides a comprehensive description of the complexities of compliance under The Federal Food, Drug, and Cosmetic Act (FDC Act) and practical suggestions on how FDA-regulated entities can avoid being the subject of an enforcement action by the federal government. PLI's new **FDA Deskbook** explains the legal framework created by the FDC Act and subsequent statutes, regulations, guidance and policies governing the food and drug industry.

Written by attorneys at Hyman, Phelps & McNamara, P.C., the largest dedicated food and drug law firm in the U.S., the **FDA Deskbook** incorporates more than a century of cumulative experience from positions at FDA, the U.S. Department of Justice, the Drug Enforcement Administration, U.S. Attorney's Offices, and regulated industry. The result is this essential guidebook, which aims to assist industry stakeholders by providing a wide-ranging review of compliance and enforcement under the FDC Act and related laws.

The **FDA Deskbook** first details the ins-and-outs of FDA's administrative actions (such as warning letters, import alerts, and recalls) and civil and criminal enforcement authorities. The **FDA Deskbook** then walks the reader through individual chapters highlighting specific issues affecting the cross-section of FDA regulation:

- drugs, including OTC, prescription, and compounded drugs, and controlled substances
- medical devices, including in vitro diagnostic devices
- food and dietary supplements
- tobacco
- animal products
- cosmetics

Importantly, the **FDA Deskbook** contains chapters focused on today's hot button issues, such as advertising and promotion, fraud and abuse, and good manufacturing practices. The **FDA Deskbook** proposes best practice tips, including how to deal with FDA inspections, alternatives to conducting internal investigations, and potential defense strategies for use in enforcement proceedings.

The **FDA Deskbook** provides a thorough discussion of the current landscape necessary for FDA-regulated entities to achieve compliance and avoid enforcement action.

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