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FDA Deskbook

A Compliance and Enforcement Guide

Edited by
James P. Ellison
Anne K. Walsh

Incorporating Release #2
November 2018
#239475

Practising Law Institute
New York City
#173127

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LCCN: 2016932016

ISBN: 978-1-4024-2647-6

Hyman, Phelps & McNamara, P.C.

HYMAN, PHELPS & MCNAMARA, P.C. is the largest dedicated food and drug law firm in the country. Niche practices in new drug development, controlled substances, advertising, and health care law complement our core FDA practice. Our knowledge of the laws and regulations governing drugs, medical devices, foods, dietary supplements, and cosmetics is unparalleled in breadth and depth. Due to its broad bench of expertise, the firm is well equipped to defend companies against government enforcement actions and advise clients on necessary compliance efforts. The firm's clients are as diverse as the regulatory issues they face. They range from individuals and start-up companies with no in-house legal staff to large multinational corporations. In addition, other law firms retain HPM to provide targeted expertise in food and drug law to assist their clients. HPM works to avoid legal problems when possible, and to help solve them when necessary. The firm helps companies conduct business as efficiently and profitably as possible by providing advice and counsel on meeting current and future regulatory requirements.

About the Editors

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The editors wish to acknowledge the generous contributions of other colleagues at the law firm of Hyman, Phelps & McNamara, P.C., including legal assistants Charles Snow and Scott Goldman, and administrative assistants Cora Seballos and Danette Williams. We also want to recognize the contributions of former colleagues of the firm: former directors John Fleder, Anne Marie Murphy, Jennifer Newberger, and Roger Thies; former associates Joseph (Jay) Cormier, Andrew Hull, William Koustas, James Shehan, Jenifer Stach, Jamie Wolszon, and Etan Yeshua; and former law clerk Lauren Farruggia and legal assistant Alli Katzen.

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Preface

The Federal Food, Drug, and Cosmetic Act (the "FDC Act"), first enacted in 1938, is the most important public health and consumer protection law in the United States. The FDC Act regulates about 25% of the U.S. economy, affecting the health and well-being of the entire population. Compliance with that law is essential to the public and to the economic health of the country.

Starting out as a brief, straightforward statute designed to assure that foods, drugs, and cosmetics are safe for their intended uses, the FDC Act is now almost encyclopedic in size and complexity. To highlight this growth, compare the tenfold increase in the pages required to publish the FDC Act in the official version of the U.S. Code, from forty-five pages in 1940 to 480 pages in 2012. Lengthy and complicated provisions now address the approval of new drugs for humans and animals, approval or clearance of medical devices, manufacturing practices, record-keeping, and regulation of tobacco products. The efforts and interests of Congress, the regulated industries, the medical and academic communities, the media, self-styled consumer representatives, and even, occasionally, the lay public have all contributed to this growth.

The U.S. Food and Drug Administration (FDA) has contributed to the overwhelming complexity of the regulatory climate by issuing regulations, policies, and guidances of varying degrees of legal authority. The regulations alone take up more than 4,000 pages of small print, in eight volumes (for 2015) of the Code of Federal Regulations. They cover virtually every aspect of the agency's regulatory authority.

As the administrative agency established to enforce the FDC Act, FDA has grown in size, expertise, and responsibilities, commensurate with the FDC Act itself. FDA's 15,000-plus employees are responsible for regulating the safety and, where appropriate, efficacy of the foods, drugs, cosmetics, biologics, veterinary medical products, medical devices, radiological products, and tobacco products produced, imported, and marketed in the United States.

Despite the gargantuan growth of the statute and accompanying regulations and guidance over the last eighty years, FDA's basic tools for enforcement have not changed much. The FDC Act defines "prohibited acts" and authorizes FDA, through the Department of Justice, to bring actions in the federal courts to seize violative products, enjoin companies and individuals from violating the Act,

and prosecute companies and individuals for violating the Act. The same acts can give rise to any of those remedies. Moreover, the U.S. Supreme Court has affirmed the proposition that any individual who stands in a responsible position with respect to an FDC Act violation may be convicted of a criminal violation of the Act without proof of specific intent, knowledge, or even awareness of the violation. The criminal fines have increased exponentially, but the potential imprisonment remains the same (one year per misdemeanor count; three years per felony count) as in the original 1938 legislation.

More recent amendments to the FDC Act have added other formal enforcement tools that FDA itself can impose, including substantial civil money penalties for various violations of the Act involving prescription drugs, medical devices, pesticide residues in food, and clinical trials. In addition, FDA can debar a business or individual from working for pharmaceutical companies or participating in food imports or certain device activities, based on a criminal conviction.

Added to those statutory tools is FDA's first line of informal regulatory actions—warning letters, untitled letters, recalls—giving FDA a full arsenal of weapons to enforce the law. These administrative, civil, and criminal enforcement powers are evaluated in the first three chapters of this book, and are followed by chapters providing in-depth discussion of issues related to product-specific compliance and enforcement activities.

In the face of this comprehensive regulatory framework, compliance is the goal for industry, government, and consumers. It is essential for all who participate in the production and distribution of products subject to the FDC Act to be as fully informed about and conversant with these requirements as possible.

The authors of this book are attorneys at Hyman, Phelps & McNamara, P.C. (HPM), the largest dedicated food and drug law practice in the United States. The firm was founded in 1980 with the goal of providing service to clients regulated primarily by FDA, the agency with which the three founders had extensive experience. HPM has since added more attorneys who have worked at FDA, along with attorneys with regulatory and enforcement experience from other government agencies such as the U.S. Department of Justice, the Drug Enforcement Administration, U.S. Attorneys' Offices, and regulated industry. This expertise has helped countless companies successfully avoid enforcement action and comply with FDA laws, regulations, and guidance.

This book, borrowing from more than a century of cumulative experience in the field, is intended to assist stakeholders by explaining the labyrinthine requirements of the FDC Act, and to describe enforcement that may result from lack of compliance, if the lessons of compliance cannot otherwise be learned.

Although this book provides a comprehensive review of compliance and enforcement of the FDC Act today, it cannot be the last word on these issues. Different individual circumstances will dictate different results, and the regulatory process—and indeed the regulated industries—continue to evolve. New facts, products, needs, and concerns will arise, requiring innovative responses by stakeholders, FDA, and possibly lawmakers.

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