

FOOD AND DRUG LAW

Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products

11th Edition

By Roseann B. Termini, Esq.

- New edition reflects updates to every section which include COVID-19 pandemic and the Opioid Epidemic
- The only “all-in-one” comprehensive book covering multiple areas of food and drug law
- “Go-to” resource with clear, plain language
- Practical road map for a complex area of law



ABOUT THIS TITLE

Food and Drug Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods, Dietary Supplements, Personal Care, Veterinary and Tobacco Products, 11th Edition, is an “all-in-one” comprehensive book, organized for ease of reading this complex area of federal regulatory law. There is a separate section for each subject based on regulation under the United States Federal Food, Drug and Cosmetic Act (FDCA) and related laws all contained in this bound book. It is organized into separate subject-specific sections with a concise introduction to provide a particular focus for the reader.

NEW IN THE 11TH EDITION

Every section in this edition is updated to reflect current laws, including the COVID-19 pandemic and the opioid epidemic

The 11th edition of *Food and Drug Law* features the **food and drug law administrative primer** (banned devices), **criminal and civil enforcement strategies** (corporate accountability), **medical device regulations** (updated pathways), **human drug regulation** (opioids epidemic), **biotechnology regulation** (COVID-19 vaccines), **veterinary products regulation** (unsafe pet products), **personal care products regulation** (product classification), **food regulation** (recent recalls), **dietary supplements** (kratom), **tobacco regulation** (e-cigarette and vaping enforcement), and many more!

THIS IS A GO-TO RESOURCE FOR

- The **regulated industry**, such as legal counsel and regulatory affairs personnel, searching for concise explanations of relevant portions of the Food, Drug and Cosmetic Act (FDCA)
- **Legal practitioners** in issues involving food, medical devices, drugs, biologics, cosmetics, veterinary, dietary supplements, and tobacco products regulatory law
- **Government personnel**—federal, state, and local—involved in these topics
- **Attorneys** in related disciplines who find themselves in the crosshairs of the FDCA
- The **academic community**, including medical, pharmacy, law, and regulatory affairs

ABOUT THE AUTHOR

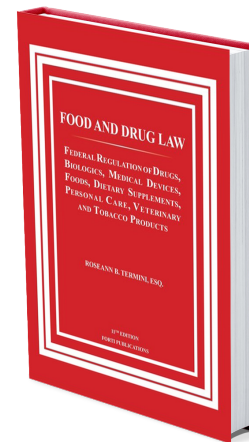
Roseann B. Termini, Esq., has more than thirty years of extensive experience in food and drug law. Further, she has published on a broad array of specialized food and drug law issues such as corporate accountability, criminal liability, enforcement, health claims, supplements, safety, duty to warn, preemption, regulation, promotion, tobacco, stem cells, risk assessment, and globalization. She is a speaker nationally and internationally and was the first awardee of the Plain English Award. Termini initiated the inaugural online food and drug law courses at Widener University School of Law and the direct-to-consumer promotion at St. Joseph’s University executive program. She served as the sole corporate counsel for an FDA-regulated company and senior deputy attorney general, Pennsylvania Office of Attorney General. Besides her professional association committee appointments, she served on the President’s Council at Immaculata University, served as Food and Drug Law Institute Committee Chair, and is a member of the Central Atlantic Association of Food and Drug Law Officials. Termini is co-chair of the Health Law Committee of the PA Bar Association and was admitted to the Bar of the United States Supreme Court in 2018.

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