Code of Federal Regulations

FDA Guidances

2019

Book 7

Selected Laws, Regulations & Guidance on Drug Marketing, Advertising and Labeling

(April 1, 2019 - March 31, 2020)

Federal Food, Drug and Cosmetic Act

(selected sections)

CFR Title 21 Food & Drugs

Revised as of April 1, 2019

Part 99: Dissemination of Information
Part 200: General
Part 201: Labeling
Part 202: Prescription Drug Advertising
Part 203: Prescription Drug Marketing
Part 206: Imprinting of Drug Products
Part 208: Medication Guides
Part 299: Official/Established Names of Drugs
Section 312.7: Promotion of Investigational Drugs
Section 314.81: Other Postmarketing Reports
Section 314.550: Promotional Materials
Section 314.560: Termination of Requirements

FDA Guidances

- Industry-Supported Scientific and Educational Activities
- Consumer-Directed Broadcast Advertisements
- Qs & As on Consumer Broadcast Advertisements
- Clinical Studies Section of Product Labeling
- Adverse Reactions Section of Product Labeling
- Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format
- Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling
- Labeling for Human Prescription Drug and Biological Products — Implementing the PLR Content and Format Requirements

CLINICAL RESEARCH RESOURCES