KILPATRICK TOWNSEND

FDA Regulation

Conflicting Demands

Pharma, medical device, food, and cosmetics companies face enormous challenges from global competitors and regulatory frameworks seeking to balance public safety and innovation. At the same time, technology and patient demands have led to enormous opportunity in areas such as digital health and clinical trial innovation. We understand these complexities and help companies navigate the regulatory landscape throughout the lifecycle of their products — from development to marketing — all while maintaining a constant focus o business objectives.

Reach

Emerging Markets

Our team develops effective strategies for market entry and for meeting FDA requirements, and also provides corporate due diligence in acquisitions, sales, and mergers of companies in both traditionally regulated sectors, as well as emerging treatment options. Our multidisciplinary team uses an integrated approach when providing effective and efficient legal services to FDA-regulated companies, including handling client matters before the Federal Trade Commission (FTC), Consumer Product Safety Commission (CSPC), and the National Advertising Division of the Better Business Bureau (NAD).

Approach

Technicalities

Kilpatrick Townsend's FDA Regulatory Practice Group includes professionals who have a specialized cross-industry understanding of areas, including health care, life sciences, and technology — all of which are relevant to the lifecycle of an FDA-regulated product.

- Prescription Drug Promotion & Advertising
- Patent Term Extensions & Exclusivity Matters, including Orange Book listings
- Registration & Listings of Over-The-Counter (OTC) Drugs & Medical Devices
- Pharmaceutical & Biologic Investigational New Drugs (IND), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biologics License Applications (BLAs) & Biosimilar Submissions
- 510(K) Premarket Notifications, Investigational Device Exemptions (IDEs) & Premarket Approvals (PMAs)
- Medical Mobile Applications (MMAs) & Cybersecurity
- FDA Ingredient & Claims Review, Labeling & Advertising of Foods, Dietary Supplements, Medical Foods, OTC Drugs & Personal Care Products
- Responses to FDA Form 483 & Warning Letters
- Product Recalls & Market Withdrawals
- Matters Related to the Import & Export of FDA Regulated Products

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