Wiley Rein’s Food, Drug, and Medical Device Law Practice has the depth of experience and breadth of resources to effectively handle complex legal and regulatory challenges, as well as the more routine but crucial regulatory tasks required of U.S. Food and Drug Administration (FDA)-regulated companies in the pharmaceutical, biotechnology, medical device, food, and dietary supplement industries. Our team members include attorneys who have worked at the FDA and as in-house counsel at large consumer product companies, and who have received independent recognition from numerous organizations as leaders in food and drug law.

We offer comprehensive services in the following broad areas:

- **Regulatory compliance** (assistance with appropriate responses to Warning Letters, Untitled Letters, Application Policy Letters, Clinical Investigator Disqualification Letters, and Clinical Hold Letters);
- **Product development and approval strategies** (Premarket Approval Applications and Premarket Notifications for the marketing of medical devices, New Drug Applications for the marketing of innovator and generic drugs, Biologics License Applications for innovator and biosimilar products, and Investigational New Drug and Investigational Device Exemption applications for the clinical testing of investigational products);
- **Recalls** (assisting companies that manufacture and distribute FDA-regulated products throughout the recall process);
- **Promotion and advertising compliance and enforcement** (FDA and Federal Trade Commission (FTC) regulation of advertising for prescription (Rx) and over-the-counter (OTC) drugs, medical devices, foods, and dietary supplements);
- **Due diligence and transactional support** involving FDA regulatory issues (mergers & acquisitions, product acquisitions, licensing agreements, joint ventures, initial public offerings (IPOs), venture funding);
- **Administrative advocacy and litigation** before agencies and the courts (FDA meetings, administrative appeals, citizen petitions, Administrative Procedure Act (APA) litigation);
- **Competitive regulatory strategies** (lifecycle management, Hatch-Waxman patent litigation support); and
• Enforcement and white-collar defense.

INDUSTRIES SERVED

Our practice cuts across all industry sectors regulated by the FDA, including medical devices and radiation-emitting products (whether for medical or non-medical purposes), pharmaceuticals and biologics, foods and dietary supplements, and cosmetics and personal care products. Many companies are subject to joint or overlapping regulation by the FDA, the FTC, the Consumer Product Safety Commission (CPSC), and analogous state agencies. Below we summarize the nature and scope of the regulatory oversight of these industry sectors and our capabilities in these areas of regulation.

• Medical Devices
• Non-Medical Radiation Emitting Devices
• Pharmaceuticals
• Human and Animal Food
• Dietary Supplements
• Personal Care Products

Contact Us

Tracy Heinzman
202.719.7106 | theinzman@wileyrein.com