FDA Regulatory

Michael Best's broad-based FDA Regulatory practice covers the full gamut of matters related to the U.S. Food and Drug Administration (FDA) and other product regulation agencies. Whether a client's product is food, drugs, medical devices, software, cosmetics, dietary supplements, or lasers, we have the experience to match.

Our FDA Regulatory group is multidisciplinary and cross-practice. Not only do we have the right attorney for any FDA matter, but we also collaborate across practice groups to integrate sound FDA regulatory advice into projects involving our intellectual property, environmental, and corporate groups, among others. We assist clients throughout the entire product life cycle, starting with premarket services such as:

- Product classification and developing regulatory strategies
- Preparing and prosecuting full premarket submissions for various product types (see "Industry Experience" below)
- Reviewing design control and product validation programs
- Registration, listing, and prior notice for imports

Once a product goes to market, we continue to counsel clients in matters such as:

- Production – Current Good Manufacturing Practices, Quality Systems, Hazard Analysis and Critical Control Points, and Hazard Analysis and Risk-Based Preventive Controls
- Safety – Adverse event reporting, Postmarket Surveillance Studies, Post-Approval Studies, and Risk Evaluation and Mitigation Strategies
- Compliance and enforcement – Self-audits, employee and management training, inspections, recalls, warning letters, and enforcement actions

Our industry experience gives us an in-depth understanding of FDA-regulated businesses.

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Because of our wide-ranging experience, we can readily advise on issues that cross over product types, such as identifying the distinctions between dietary supplement claims and drug claims, or between cosmetic claims and medical product claims. We also assist clients with issues involving multiple regulatory agencies, such as the interplay between FDA and the FTC in regulating advertising, the control of narcotics and other substances by FDA and the DEA, and the food safety system overseen by the U.S. Department of Agriculture and FDA.

Experience

Medical Devices

We prepare and prosecute a full range of medical device regulatory submissions, including premarket notifications (510(k)'s), Premarket Approval Applications, and de novo submissions; advise on reporting adverse events and conducting corrections and removals (i.e., recalls); and counsel on compliance with the Quality System Regulation. Our attorneys handle highly technical regulatory issues such as design controls, export controls, medical device clinical trials, and Lanham Act litigation.

Medical Software

We help clients navigate the complex regulation of medical software, including Mobile Medical Apps and telemedicine solutions. We understand how medical software is developed, including the importance of software design controls in the premarket submissions to FDA, as well as the regulatory roles played by the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Michael Best's experience includes handling these and other FDA regulatory issues such as cybersecurity, cloud computing services, and software validation.

Food and Dietary Supplements

We have experience in advanced manufacturing compliance issues such as FDA's Current Good Manufacturing Practices (CGMPs) and Hazard Analysis and Critical Control Point (HACCP) requirements. Our counsel includes helping clients develop recall strategies; handling import requirements and removal from import alerts; drafting labeling, including "Nutrition Facts" and "Supplement Facts" panels; advising on advertising claims, including permitted structure/function claims; and helping clients understand and comply with evolving regulations under the Food Safety Modernization Act.

We also assist with preparing New Dietary Ingredient notifications, Food Additive Petitions, and Generally Recognized As Safe self-certifications.

Drugs and Biologics

Our FDA Regulatory team advises pharmaceutical and biomedical clients on CGMP regulations and guidance, including those applicable to Active Pharmaceutical Ingredient manufacturers; premarket regulatory strategies; New Drug Applications; compliance with clinical trial regulations; Hatch-Waxman and orphan drug exclusivity; compliance with Over-the-Counter drug monographs; biosimilar products; and Citizen Petitions.

Our depth includes technical regulatory issues such as immunogenicity and generic applications for discontinued drug formulations. We also prepare and submit drug registration and listing submissions for clients following FDA's Structured Product Labeling scheme.

Agriculture

Michael Best has a long, deep history with the agricultural industry, which extends into federal regulatory issues. We advise clients on all aspects of compliance with FDA's regulation of raw agricultural products and farm-produced foods (such as ciders and juices); handle matters involving the regulation of veterinary drugs and animal feed, including enforcement matters; and advise on regulation by the U.S. Department of Agriculture, such as the Federal Seed Act and labeling requirements for rBST.

Electronic Products

We assist clients with meeting regulatory requirements for radiation-emitting electronic products in medical and commercial settings. We prepare Radiation Safety Product Reports and Annual Reports, and we advise on ongoing compliance with the unique regulatory schemes applicable to laser products, microwave ovens, and commercial X-ray and other imaging systems.

Our experience gives us an intimate understanding of FDA's inspection authority over commercial radiation-emitting electronic products, as well as the interplay between FDA's medical device regulations and electronic product regulations.