SheppardMullin

FDA Regulatory

Sheppard Mullin attorneys counsel clients whose activities are regulated by the U.S. Food and Drug Administration (FDA). We represent companies across an array of industries — pharmaceutical, biologic, biotechnology, medical devices and digital health, food and beverage, dietary supplements, and cosmetics — on matters spanning the entire product lifecycle, from concept to commercialization. We bring an innovative and business-oriented approach to resolving complex legal and regulatory issues that complements our clients' cutting-edge technologies and novel products.

We also provide advice on comprehensive compliance programs and risk management strategies, advertising and promotional rules, product labeling, FDA exclusivity, industry guidances, licensing transactions, and regulatory enforcement actions, including DOJ investigations and corporate integrity agreements.

The FDA Regulatory Team brings a unique understanding of the development and commercial challenges facing life sciences companies. Many of our attorneys have deep in-house or secondment experience, setting us apart from traditional outside counsel.

Development and Pre-Market Regulatory Navigation

We counsel companies and investors on the FDA regulatory status and approval pathway of proposed new products and concepts, including strategies for product positioning on novel technologies. We work with clients during the research and development phases on issues concerning the conduct of pre-clinical and clinical studies, FDA market exclusivity options, and, in consultation with patent attorneys, patent strategies for maximizing product life.

Comprehensive Compliance Programs

We help companies assess, develop, and implement effective and efficient compliance programs, including policies, standard operating procedures, and work instructions related to the development and promotion of FDA-regulated products. We often devise, monitor, and revise compliance programs and, if necessary, conduct internal investigations to detect and remedy problems before they cause more damage.

Training

We often provide training to all levels of employees, from field representatives to executives, in order to meet the needs of companies' compliance programs. Our customized trainings cover a wide variety of topics from False Claims Act, anti-kickback statutes, and Prescription Drug Marketing Act to promotional rules and regulations.

Labeling, Promotion and Advertising

We advise clients regarding product labeling, promotion, and advertising requirements of the FDA and FTC, including label requirements, claims substantiation, false and deceptive advertising, and First Amendment protection. We have extensive experience protecting our clients and their brands from false advertising and product labeling claims. We regularly counsel and review all types of promotional and scientific materials for FDA-regulated products. We often sit on a client's promotional or scientific review committee.

Contracts

We draft, review, and negotiate a wide range of contracts for clients, including clinical trial and site agreements, supplier, wholesale and distribution agreements, as well as health care practitioner consulting agreements.

Sample Distribution and Licensing

We have extensive experience counseling on The Prescription Drug Marketing Act and state manufacturers and distribution licensing requirements.

Monitoring and Gap Assessments

We help manufacturers ensure adherence to their compliance programs and corporate integrity agreements. We regularly assist in monitoring promotional activities, such as speaker programs, and conduct ride alongs with field representatives.

Investigations

We aggressively represent individuals and corporations in a broad spectrum of high stakes government inquiries, investigations, and proceedings. We defend against all manner of allegations, including health care fraud and False Claims Act, and have dealt with every major prosecutorial and investigative agency on multiple occasions, including the FDA.

Due Diligence and Corporate Transactions

We advise funds and companies acquiring or selling FDA- regulated entities/ assets and on corporate transactions and agreements involving FDA-regulated products/activities. We also negotiate distribution agreements, licensing agreements, supply agreements, quality agreements, and clinical trial agreements.

Product Safety, Inspections, and Post-Market Issues

We handle a range of post-marketing issues arising under the Federal Food, Drug, and Cosmetic Act (FDCA), such as product recalls and adverse events, field alerts and device corrections, compliance with CGMP/QSR, supplemental approvals, compliance with the Food Safety Modernization Act (FSMA) and marketing/labeling issues, including organic labeling. We handle complicated legal and regulatory aspects of inspections and audits, including representing clients before the FDA and U.S. DOJ, conducting cGMP and QSR audits and data integrity reviews and assisting clients in responding to agency enforcement actions, including 483s and Warning Letters.

Regulatory Strategies for Novel Products, Including Hemp/CBD

We help clients craft regulatory strategies for novel products and ingredients, including products containing hemp and CBD, and assist cannabis businesses with a wide array of matters, including compliance with the FDCA, federal and state Controlled Substances Acts, and state/ local regulation.

Brand Name Identification and Protection

We work with clients to craft a strategic approach to the acquisition, maintenance, and defense of rights, including trademarks, copyrights, patents, trade secrets, and other types of intellectual property.