FDA Regulatory

Skadden

Skadden's comprehensive FDA regulatory experience spans all product areas regulated by the agency, including prescription and over-the-counter (OTC) drugs, medical devices — including laboratory-developed tests, combination products and digital health products — cosmetics, dietary supplements and food.

We assist companies with understanding and managing regulatory risks and associated business impacts related to all manner of FDA-regulated products, ranging from gene therapies to sunscreens to collagen supplements. Our longstanding experience serving at and working with FDA helps us develop creative solutions to address our clients' mission-critical challenges.

Prescription Drugs

Skadden advises on all aspects of prescription drug approval and commercialization — including investigational new drug (IND) applications, new drug applications (NDAs) and abbreviated new drug applications (ANDAs) — and can assist clients in navigating clinical trial requirements and expedited approval pathways. We are well-positioned to help clients ensure compliance with Current Good Manufacturing Practice (cGMP) regulations involving quality systems, process validation and post-marketing requirements. Additionally, we can support clients' needs with respect to advertising and promotion, including supporting promotional review activities and advising on FDA requirements for prescription drug advertising. Our team also has experience advising controlled substance manufacturers on both Drug Enforcement Administration (DEA) and state regulatory requirements.

In the biologics sphere, we have experience navigating the Biologics License Application process; addressing enhanced regulatory requirements; and helping demonstrate safety, purity and potency. Our team is able to guide clients through the complexities of biosimilar development.

OTC Drugs

Our team has extensive experience in the development, approval and marketing of OTC drugs, as well as relevant cGMP requirements. We can assist clients in complying with established OTC monographs or obtaining approval through the NDA process, and are well-versed in the nuances of Rx-to-OTC switch requirements. Additionally, we have experience in OTC drug development, monograph compliance, new ingredient reviews and safety assessments, as well as labeling and marketing (including claims substantiation and e-commerce requirements). We are well-positioned to offer guidance on quality control programs, safety testing protocols and adverse event reporting.

Medical Devices and Combination Products

Our team provides comprehensive guidance to our clients on medical devices, digital health products and combination products covering Class I, II and III devices. We can help clients navigate the 510(k)/De Novo clearance process, premarket approval and investigational device exemptions, as well as ensure compliance with updated Quality System Regulation requirements. We also have experience in medical device reporting, device labeling and marketing policies, and are well-versed on FDA regulatory requirements for software as a medical device and AI/machine learning-based software. Our team also helps clients understand the nuances of regulatory frameworks for digital health products, including the FDA's enforcement discretion for low-risk products.

Our attorneys also are adept in identifying the primary mode of action for combination products and navigating the specific design, manufacturing and testing requirements. We are well-equipped to address challenges our clients face in developing drug-device combination products, such as prefilled syringes or drug-eluting stents.

FDA Regulatory

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Cosmetics

Skadden can guide clients through the complex landscape of cosmetics regulations, ensuring compliance with the Modernization of Cosmetics Regulation Act. We also are able to assist clients in creating compliant labels, packaging and safety substantiation, and establishing processes for adverse event reporting. As future cGMP requirements loom in this area, we are positioned to help clients prepare by choosing manufacturers equipped to meet these standards, ensuring comprehensive regulatory compliance.

Dietary Supplements

Our attorneys have experience advising clients on the development and marketing of dietary supplements, ensuring compliance with the Dietary Supplement Health and Education Act of 1994. We are able to assist manufacturers with new dietary ingredient notifications, cGMP requirements and proper labeling. We also can support dietary supplement manufacturers to develop evidence for structure/function claims. Additionally, we have extensive experience in product development, compliance, marketing and e-commerce — including monitoring customer reviews — in this area.

Food

Our group has unparalleled experience in navigating the complexities of food safety and compliance. We are able to assist wholesalers, distributors and retailers in meeting the stringent requirements of the Food Safety Modernization Act, including supplier verification, food defense plans and sanitary transportation practices. Our team also can help develop hazard analysis and risk-based preventive controls, maintain written food safety plans, register facilities with FDA and review Global Food Safety Initiative certification. Additionally, our attorneys can provide guidance on food labeling requirements, such as Nutrition Facts panels and allergen declarations, and address specific regulations.

Product Safety

Skadden is able to advise on Consumer Product Safety Commission (CSPC) compliance, including safety assessments, labeling and recall management. Our attorneys can assist with CPSC proceedings and develop custom compliance strategies for our clients' specific needs. In addition, we have experience helping clients navigate regulatory requirements for e-commerce and third-party marketplaces, ensuring compliance with trade, consumer protection and product safety standards, while also balancing regulatory obligations with user experience.

FDA Enforcement Action

Skadden advises clients on a range of FDA enforcement actions, including inspections, 483 responses, import alerts, recalls, consent decrees, product seizures, injunctions and criminal prosecutions. Our team also helps clients navigate warning letters, corrective actions and follow-up audits.