

FOOD AND DRUG REGULATORY

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Sheppard Mullin has a full service FDA team as part of its Life Sciences practice group. Our attorneys represent manufacturers and distributors of prescription and OTC drugs, biologics, medical devices, cosmetics, dietary supplements and food, as well as other entities whose activities are regulated by the U.S. Food and Drug Administration (FDA), including advertising agencies, clinical investigators, and research organizations.

Our comprehensive experience includes advising and assisting our clients on all phases of product development and approval and ensuring compliance with the Federal Food, Drug, and Cosmetic Act; the Public Health Service Act; the Controlled Substances Act; and related federal and state laws and regulations. They regularly advise clients on advertising and labeling compliance, recalls, manufacturing issues, and other post marketing regulatory requirements. Our attorneys have also been involved in the representation of trade associations of FDA regulated industries on regulatory and legislative issues, including the Compressed Gas Association, HDMA, and the International Wheat Gluten Association.

Our work is vast in scope. It begins in the planning and research and development phases and includes, for example, counseling on issues concerning strategies for product positioning, the conduct of pre-clinical and clinical trials, and FDA market exclusivity options. As part of the submission phase of product development and approval, we advise and assist clients on a wide array of issues, including, for example, the preparation and submission of marketing applications and user fees, helping to facilitate meetings with FDA during the Agency's product review, and assisting in the preparation for pre-approval inspections. Our work with, and on behalf of, our clients continues on a host of post-marketing issues. Such issues include, for example, establishment registration and product listing, adverse event and other reporting and recordkeeping requirements, import-export issues, compliance with current good manufacturing practices (cGMPs), obtaining supplemental approval for new uses and product life cycle issues, responding to formal and informal agency enforcement actions, and all aspects of marketing, including, labeling, advertising and promotion issues.

Our attorneys also have extensive experience in conducting regulatory compliance due diligence audits of potential acquisition targets and assessing compliance in preparation for regulatory audits by FDA and DEA. In addition, our attorneys are skilled in representing clients before executive agencies in administrative rulemaking, litigation, and licensing matters.