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FDA and USDA Regulatory Compliance

We advise companies of all sizes on compliance with U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) regulations, guidance, policies, and procedures regarding drugs, medical devices, human and animal foods, agricultural products, dietary supplements, and cosmetics. Our compliance counseling experience spans a broad range of contexts including but not limited to:

- Drug and Device Compliance:
    - Development of effective compliance programs for pharmaceutical manufacturers, including standard operating procedures (SOPs), employee codes of conduct, internal investigations, self-reporting and post product approval product management;
    - Assist all actors in the medical device field with premarket issues, market entry strategies, and postmarket compliance. This includes compliance reviews and liability exposure assessments, medical device reporting compliance, good manufacturing practices (GMPs) and quality system regulation (QSR) compliance, and medical device reporting (MDR).
    - Supporting clinical and pre-clinical research related programs, such as those related to institutional review board (IRB) approval, pre-clinical testing review, clinical trial development and review (including design and protocol assistance), and FDA and related agency submission and reporting requirements;
    - Change reporting and supplemental application requirements for drugs;
    - OTC monograph requirements for drug product formulation, labeling, and testing;
    - Product safety monitoring and adverse event reporting;
    - Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP);
    - Advising on drug and medical device advertising, marketing, and promotional strategies and compliance.
- Food Safety and Regulatory Compliance
    - Food GMPs and Food Safety Modernization Act compliance, involving hazard analysis, preventive control and corrective action plans, supplier verification programs, track-and-trace, and recordkeeping requirements;

    - Product development, as well as formulation, labeling, and claims including permissible product ingredients, health claims, nutrient content, and "structure/function" claims for legacy and emerging foods and dietary supplements;
    - Matters involving the USDA Food Safety and Inspection Service (FSIS), as well as other USDA agencies such as the Agricultural Marketing Service (AMS) and the Animal and Plant Health Inspection Service (APHIS);
    - Advising on food, dietary supplement and cosmetic advertising, marketing, and promotional strategies and compliance.

- Cross-Cutting Product Category Compliance
    - Import and export requirements, international trade (customs and country-of-origin matters, European Union (EU) regulation and policies);
    - Preparing for and responding to regulatory inspections and other regulatory actions.

In addition, we have unparalleled expertise in matters that fall within the interstices of FDA and U.S. Environmental Protection Agency (EPA) regulatory jurisdiction under both the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act. Complex questions can arise concerning which agency regulates certain antimicrobial substances in various contexts, as well as what differing regulatory requirements may apply depending on which agency has jurisdiction. In addition, organisms and products that fall within the scope of the *Coordinated Framework for the Regulation of Biotechnology* are subject to differing requirements depending on the stage of commercial development and the agency asserting jurisdiction.

Contact Us

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