U.S. Food and Drug Administration

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Increasing governmental regulation and enforcement by the U.S. Food and Drug Administration (FDA) has created new challenges, as well as opportunities for innovation and market development. We understand the complexities of these challenges and offer clients strategic solutions to help them successfully navigate the regulatory landscape throughout the life cycle of their products.

Our team works with pharmaceuticals, over-the-counter (OTC) drugs (including homeopathic medicines), dietary supplements, medical device, food, and cosmetic companies on developing effective market entry regulatory strategies, as well as navigating the numerous FDA requirements related to these products. We have first-hand experience working with the FDA and can offer “real-time” feedback from regulators. Because providing effective and efficient legal services to the FDA-regulated companies requires a multidisciplinary integrated approach, our team can also assist clients with any advertising, antitrust, and other related matters, that may be brought by the Federal Trade Commission (FTC), Consumer Product Safety Commission (CPSC), and/or the National Advertising Division (NAD). We also have the expertise to assist clients with establishing or developing their U.S. corporate presence, including assessment of corporate structure and related tax implications, and due diligence in acquisitions, sales, or mergers of FDA-regulated entities.

For current updates on the FDA, please visit our blog FDAConneKTion [1].

DRUGS AND BIOLOGICS [2]

- Pharmaceutical and Biologic Investigational New Drugs (INDs), New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biologics License Applications (BLAs) submissions, and Biosimilar submissions
- Prescription drug promotion and advertising, patent, and exclusivity matters, including Orange Book listings
- Registration, listing, and adverse event reporting
- Cellular, Tissue, and Tissue Products (human and veterinary) regulatory requirements
- OTC and homeopathic drug labeling and advertising, including review of monograph ingredients and claims, as well as assessment of FDA and FTC enforcement risk for these products

MEDICAL DEVICES [3]

- Medical device classifications, 510(k) notifications, Investigational Device Exemptions (IDEs), and premarket approvals (PMAs)
- *In vitro* Diagnostics
- Medical mobile applications (MMAs)
- Telemedicine and medical device software
- Registration, listing, and adverse event reporting
- Cybersecurity and risk management

ENFORCEMENT, IMPORTS, AND INSPECTIONS [4]

- FDA inspections
- FDA Form 483 and Warning letters responses
- Product recalls and market withdrawals
- Import and export of FDA-regulated products

FOODS AND DIETARY SUPPLEMENTS [5]

- Food ingredients and labeling, including claims and advertising
- Dietary supplements ingredients, labeling, advertising, and claim substantiation
- New Dietary Ingredients (NDIs)

- Compliance with Good Manufacturing Practices (GMPs)
- GRAS Notifications, food additives, and food contact materials submissions
- Food Safety Modernization Act (FSMA)
- Natural, organic and gluten-free and GMO claims

COSMETICS AND PERSONAL CARE PRODUCTS [6]

- State regulation of ingredients and other claims (e.g., Proposition 65)
- FDA ingredient and claims review, labeling, and advertising