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FDA Regulatory Compliance

We advise companies on compliance with U.S. Food and Drug Administration (FDA) regulations, guidance, policies, and procedures regarding drugs, medical devices, human and animal foods, dietary supplements, and cosmetics. Our compliance counseling experience spans a broad range of contexts including:

- Development of effective compliance programs for pharmaceutical manufacturers, including standard operating procedures (SOPs), employee codes of conduct, internal investigations, and self-reporting;
- Informed consent, institutional review board (IRB) approval, and clinical trial registration and reporting;
- Pharmaceutical and food advertising and promotion;
- Change reporting and supplemental application requirements for drugs;
- OTC monograph requirements for drug product formulation and labeling;
- Product safety monitoring and adverse event reporting;
- Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP);
- Product formulation, labeling, and claims including permissible product ingredients, health claims, nutrient content, and "structure/function" claims for foods;
- Assist all actors in the medical device field with premarket issues, market entry strategies, and postmarket compliance. This includes marketing and promotional strategies, compliance reviews and liability exposure assessments, medical device reporting compliance, cGMP and quality system regulation (QSR) compliance, and medical device reporting (MDR).
- Food Safety Modernization Act compliance, involving hazard analysis, preventive control and corrective action plans, supplier verification programs, track-and-trace, and recordkeeping requirements; and
- Import and export requirements, international trade (customs and country-of-origin matters, European Union (EU) regulation and policies).

Contact Us

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