ALSTON & BIRD

Benjamin K. Wolf

Senior Associate

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Ben's training as a biomedical engineer at a cardiac device company and as regulatory counsel at the FDA helps him advise drug, device, food, and tobacco manufacturers.

Benjamin Wolf is a senior associate in the Health Care Group and a member of the Food, Drug & Device/FDA Team. Ben counsels clients in many industries regulated by the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA). He has particular interest and experience in medical devices and agency compliance action, as well as the regulation of food, beverages, animal feed, dietary supplements, and tobacco products.

In his role in industry, Ben developed medical devices, assisted with regulatory applications, and worked to address regulators' questions. At the FDA, Ben reviewed product applications, conducted inspections, and developed policies for submission review, inspections, recalls, and other post-market issues with focuses on medical devices, combination products, and tobacco (including e-cigarettes). In private practice, Ben has worked extensively in prominent FDA regulatory firms on matters involving tobacco, food, animal feed, dietary supplements, cannabis, and cannabidiol (CBD) products.

Representative Experience

- Assisted with the submission of an Investigational New Drug (IND) application on behalf of the developer of a SARS-CoV-2 vaccine. Alston & Bird's work included a protocol review, as well as advice regarding the delivery system for the vaccine and assistance addressing FDA questions regarding the application.
- Designed, directed manufacturing procedures, and ensured regulatory compliance of medical devices.
- Developed policies and standards for post-market regulation of laboratory-developed tests (LDTs), the manufacture of medical devices, submission review, inspection, and FDA enforcement.
- Assisted makers and importers of food, raw pet food, baby formula, and tobacco products in conducting recalls.
- Advised clients marketing cannabidiol (CBD) and cannabis products on the legality of those products on a federal level and in label review, marketing, and business risk.
- Audited e-vapor clients for adherence to good manufacturing practices (GMP, also known as tobacco product manufacturing practices (TPMP)) and related regulatory requirements.
- Reviewed food, animal feed, dietary supplement, and tobacco labeling for regulatory compliance, claim substantiation, and litigation risk.
- Developed client opinions on tobacco, food, animal feed, and dietary supplements.

Publications & Presentations

Publications

- "Practical Considerations for Draft Transition Plans for Devices Under EUAs or COVID Enforcement Policies," *Medical Device and Diagnostic Industry*, January 14, 2022.

- "Top Regulatory Issues for Food & Beverage Companies to Watch for in 2022," *Food Manufacturing, December 23, 2021.*
- "Food Ingredient GRAS Conclusions: What You Should Know," *Food Manufacturing,* February 15, 2021.
- "Pending Regulatory Developments for Food Innovators: Microorganisms, Cell Cultures and COVID's Impact," *Food Manufacturing,* December 10, 2020.
- "The Top 5 Regulatory Issues for US Food Launches in 2021," *New Food Magazine,* December 8, 2020.
- "Regulation of Drugs, Biologics, Controlled Substances, Cannabis, and Compounded Drugs," in A Practical Guide to FDA's Food and Drug Law and Regulation, 7th ed., Food and Drug Law Institute, 2020.

Professional & Community Engagement

- American Bar Association
- Food and Drug Law Institute (FDLI)

Education

- The George Washington University (J.D., 2013)
- Columbia University (B.S., 2003)

Admitted to Practice

- Virginia
- District of Columbia

Related Services

Health Care | FDA/Food, Drug & Device | Life Sciences | Food, Beverage & Agribusiness | FDA Compliance & Enforcement