wiley

Ann M. Begley

Partner

202.719.4585
abegley@wiley.law

Ann counsels global and domestic clients facing legal and regulatory challenges involving products and services regulated by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Federal Trade Commission (FTC). Her particular expertise includes issues related to food and food ingredients, over-the-counter (OTC) drugs, and clinical research practice, and her practice also covers dietary supplements, prescription drugs, cosmetics, medical device products, and radiation-emitting devices such as lasers.

Ann provides clients with practical guidance regarding market entry requirements, quality issues, product formulations, labeling, and advertising, and she has represented clients before the FDA, the FTC, and other federal agencies in connection with enforcement-related matters such as product recalls, warning letters, civil investigative demands (CIDs), and import detentions and alerts.

Representative Matters

- Counsels clients on regulations and policies involving product lifecycle, beginning with product formulation, manufacturing facilities, supply chain, labeling, compliance claims, and advertising.
- Counsels food and animal feed organizations on FDA policies and regulations regarding food/feed ingredient petitions and notification such as food additive petitions, GRAS notifications and new dietary ingredient notifications, and new plant variety consultations, among others.

Practice Areas

Food & Drug
Environment & Product Regulation
Medical Devices

Credentials

Education
J.D., *cum laude,* Georgetown University Law Center
B.S.N., Georgetown University

Bar and Court Memberships
District of Columbia

U.S. Court of Appeals for the District of Columbia Circuit

- Regularly advises clients marketing foods, drugs, cosmetics, and dietary supplement products on labeling requirements, and advertising substantiation requirements.
- Advises clients on FDA and Federal Food, Drug, and Cosmetic Act (FFDCA) requirements for OTC monograph drugs and new drugs, including the CARES Act OTC monograph reform requirements, and Abbreviated New Drug Applications (ANDAs), New Drug Applications (NDAs), Investigational New Drug Applications, and Investigational Device Applications requirements.
- Advises institutional review boards (IRBs), sponsors, and investigators regarding regulations and policies governing FDA-regulated and federally funded clinical research, including regulations enforced by the Office for Human Research Protections (OHRP).
- Advises organizations on managing U.S. medical and food supply chain disruptions due to changing policies from the U.S. Department of Health and Human Services (HHS) and other federal agencies as a result of COVID-19.
- Represents and guides clients in responding to FDA enforcement actions such as Warning Letters, Untitled Letters, recalls, import detentions and alerts, and clinical investigator disqualification proceedings.
- Represents and guides clients facing challenges to their promotional activities from the FDA, the FTC, and the National Advertising Division (NAD) of BBB National Programs (formerly known as the Council of Better Business Bureaus).

Professional Experience

- Private Law Practice (1995-2020)
- Public Citizen Litigation Group (1994-1995)

Affiliations

- Secretary and General Counsel, Enzyme Technical Association
- General Counsel, Homœopathic Pharmacopœia Convention of the United States
- Member, Food and Drug Law Institute, 2020 Curriculum Advisor for Introduction to Food Law program
- Board Member and Chair, Inova Health Systems Institutional Review Board