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 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. 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 and strategizes with food and animal feed organizations on FDA food/feed ingredient petitions and notifications requirements, including food additive petitions, GRAS notifications, new dietary ingredient notifications, new plant variety consultations, and other food-related consultations.
- Advises clients on legal and regulatory requirements for OTC monograph drugs and new drugs, including CARES Act OTC monograph reform requirements, Abbreviated New Drug Applications (ANDAs), New Drug Applications (NDAs), Investigational New Drug Applications (INDs).

Practice Areas

Food & Drug
Environment & Product Regulation
Enforcement & Recalls
Labeling, Advertising, and Promotion
Medical Devices

Credentials

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

Bar and Court Memberships
District of Columbia Bar

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.
- Represents and guides clients facing challenges to their promotional activities from the FDA, the FTC, and the National Advertising Division (NAD).
- 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 clients in the cosmetic industry on the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), related FDA guidance, and proposed regulations.
- 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.

Professional Experience

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

Affiliations

- Secretary and General Counsel, Enzyme Technical Association (2015-present)
- General Counsel, Homœopathic Pharmacopœia Convention of the United States
- Member, Food and Drug Law Institute
  - 2021-2022 Curriculum Advisor for Introduction to Food Law program
  - 2023 Food Advertising, Labeling, and Litigation Conference Planning Committee
- Board Member and Chair, Inova Health Systems Institutional Review Board

Recognitions

- Listed by *Chambers USA* as one of "America's Leading Lawyers for Business" in Food & Beverages: Regulatory & Litigation (2023-2025)
- Included in *The Best Lawyers in America* directory for FDA Law (2022-2025)