



Lauren Petrin

ASSOCIATE

WASHINGTON, DC

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OVERVIEW

Lauren assists food systems and life sciences clients with FDA regulatory compliance.

Lauren entered law school with the intention of working in healthcare; however, her Health Law Certificate courses introduced her to Food & Drug Administration (FDA) regulatory work. Fascinated by the intersection of health and consumer protection, she accepted an internship with the FDA's Office of Legislation, an experience that gave her an inside perspective on the agency's inner workings and interactions. As an associate at her first law firm, Lauren worked with medical device companies and drug developers, reviewing their claims in light of FDA regulations, negotiating clinical trial agreements, and responding to FDA warning letters and FDA inspections.

In early 2024, Lauren joined Husch Blackwell as a member of the firm's Food Systems industry group. While she continues to work with clients in the life sciences space, her primary focus is food and agricultural organizations and trade groups, food producers, importers, and other private food companies, whom she advises on compliance with the Federal Food, Drug, and Cosmetic Act (FDCA); Federal Food Safety Modernization Act (FSMA); and other FDA regulations. She assists in the development of corporate compliance strategies, as well as with responses to enforcement actions received from the FDA or U.S. Department of Agriculture (USDA). Lauren enjoys working with such a core component of everyday life and helping companies ensure that their customers are safe.

Known as a detail-oriented, highly responsive professional, Lauren has a reputation for always having solutions ready for clients and attending every meeting with new ideas in hand.

Industry

Food Systems

Services

Advertising & Marketing

Alcohol Beverage

FDA Regulatory

Food Safety & Regulation

PFAS

Product Safety

Proposition 65

Public Policy, Regulatory & Government Affairs

Experience

HUMAN AND ANIMAL FOODS AND DIETARY SUPPLEMENTS

- Counsel food manufacturers, importers, distributors, and retailers on compliance with the various Federal Food, Drug, and Cosmetic Act (FDCA) and Food Safety Modernization Act (FSMA) regulations including Preventive Controls for Human Food and Animal Food.
- Assist clients in developing lawful labels, claims, and marketing programs for USDA and FDA-regulated products.
- Conduct regulatory due diligence reviews for both buyers and sellers of FDA-regulated entities.
- Assist in review of tariff classification and import license requirements for various food products.
- Counsel clients on compliance with California's Safe Water and Toxic Enforcement Act (Proposition 65).
- Advise clients on navigating the regulatory pathways for new human and animal food ingredients and additives.

HUMAN AND ANIMAL DRUGS AND MEDICAL DEVICES

- Counsel medical device manufacturers on compliance with FDA regulations governing the marketing and labeling of medical device products.
- Assist clients in developing claims and promotional materials for over-the-counter drug products that comport with applicable monographs.
- Advise medical device clients on strategies for obtaining a Premarket Notification, or 510(k), for a medical device product and proving substantial equivalence.

CLINICAL RESEARCH CONTRACTING

- Negotiate clinical research agreements, including clinical trial agreements, material transfer agreements, informed consent documents, and non-disclosure agreements, for both academic medical center clients and clinical research sponsors.

Experience

- Advise clients on compliance with human subjects research protection regulations.

ALCOHOL BEVERAGE REGULATION

- Assist clients on formulation and labeling for TTB and FDA regulated alcohol beverage products including wine, hard seltzers, beer, and whiskey brands.
- Counsel clients on the use of certifications on product labeling, including "vegan," "non-GMO," and "gluten free" certifications.

Education

- J.D., University of Maryland Francis King Carey School of Law
 - Health Law Certificate
 - *Journal of Health Care Law and Policy*, Manuscript Editor
- B.S., Boston University College of Communication
 - *cum laude*

Admissions

- District of Columbia



2024 Pro Bono Champion