ArentFox Schiff LLP
Attorneys

Emily Cowley Leongini

PARTNER

Emily provides strategic regulatory counsel to companies in FDA-regulated industries.

Industries

Cannabis
Consumer Products
Health Care
Life Sciences

Practices

Advertising & Promotions
Food, Drug, Medical Device & Cosmetic
— Cosmetics, OTC Drugs & Personal Care Products
— Drugs & Biologics
— Food & Agriculture
Pro Bono

International

Australia

Education

American University, Washington College of Law, JD, 2007

University of Southern California, MPP, 2004

University of Texas at Austin, BA, 2000

Offices

Los Angeles

Phone

213.443.7672

Email

emily.leongini@afslaw.com

Emily helps clients understand and mitigate risk as they develop and launch new products, manage commercial relationships, navigate post-market regulatory requirements, and respond to regulatory actions and potential crises.

Since joining ArentFox Schiff from the US Food and Drug Administration (FDA) in 2015, she has helped companies navigate legal and regulatory requirements implemented and enforced by the FDA, US Department of Agriculture (USDA), Federal Trade Commission (FTC), Drug Enforcement Administration (DEA), and their state counterparts.

Emily provides strategic advice and advocacy to small, mid-size, and large companies on a wide range of regulatory, compliance, enforcement, and transactional matters. She works with clients in virtually every FDA-regulated industry, with a particular focus on supporting consumer health, wellness, and beauty product and cannabis/hemp/CBD industries.

Her work includes:

- Reviewing proposed advertising, labeling, and promotional materials for companies that market medical devices, dietary supplements, conventional foods, cosmetics, and prescription and OTC drugs for compliance with FDA, USDA, and FTC requirements
- Providing guidance on evolving requirements imposed under the Food Safety Modernization Act (e.g., Foreign Supplier Verification Programs, Hazard Analysis and Risk-Based Preventive Controls)
- Evaluating proposed ingredients and finished formulations
- Counseling on compliance with FDA's OTC monographs (including the recent OTC monograph reforms enacted as part of the CARES Act)
- Advising on registration and listing, cGMPs, adverse event reporting, and pharmacovigilance
- Helping clients prepare for and respond to inspections, recalls, warning and untitled letters, and other enforcement actions

- Providing advice related to importation, exportation, and supply management
- Serving as the regulatory subject matter expert in consumer and competitor challenges brought under the Lanham Act and state unfair competition/false advertising laws based on product advertising and promotional claims
- Drafting and analyzing proposed federal and state legislation, regulations, and policy documents, preparing position papers and talking points, and analyzing and responding to proposed regulations and draft guidance documents
- Conducting regulatory due diligence on behalf of entities investing in and acquiring companies that market FDA-regulated products
- Drafting, negotiating, and providing guidance related to regulatory aspects of commercial agreements, e.g., agreements related to third-party research, contract manufacturing and suppliers, advertising and sponsorship, and sales and distribution

Emily also provides strategic regulatory counseling to clients in the cannabis/hemp/CBD industries on a wide array of state and federal matters. Some examples of her recent experience include:

- Advising on state laws applicable to the promotion and advertising of medical and adult-use cannabis
- Evaluating proposed ingredients and finished formulations of new cannabis/hemp/CBD products
- Reviewing proposed advertising, labeling, and promotional materials for companies marketing cannabis/hemp/CBD products for compliance with FDA, USDA, FTC, and state requirements
- Advising on federal and state requirements governing cultivation, testing, labeling, and licensing of cannabis/hemp/CBD products

Previous Work

Prior to joining ArentFox Schiff, Emily worked at FDA for six years.

Publications, Presentations & Recognitions

Publications

Emily writes frequently on food, drug, and cannabis topics. Her articles include:

- "Companies Marketing CBD Products Be Warned: FDA Is Watching," *Law360*; December 5, 2017
- "Cannabis Industry Standards: ASTM May Fill The Vacuum," *Law360*; March 7, 2017
- "3 Issues Recreational Cannabis Entrepreneurs and Investors Will Face in California," *Los Angeles Business Journal*; December 21, 2016

While in law school, Emily served as the associate executive editor of the *American University International Law Review*.

Presentations

Emily's speaking engagements include:

- "Inspections: What to Do if the Government Shows Up at Your Door," American Conference Institute's (ACI) Food Law and Regulation Boot Camp; July 23, 2025 (online)
- "Dietary Supplements," Food & Drug Law Institute (FDLI) Introduction to Food Law and Regulation; March 11, 2025 (online)
- "Dietary Supplements," Food & Drug Law Institute (FDLI) Introduction to Food Law and Regulation; September 18, 2024 (online)
-

"Legal Issues Arising From COVID-19: Key Developments in Employment, Trade, Insurance, and the CARES Act," ArentFox Schiff Webinar; April 21, 2020 (online)

- "Legal Perspective: California's Proposition 65 & Analysis of Current Litigation Trends," Q1 Productions Food Labeling: Evolving Regulatory Compliance Conference; February 11, 2020 (Alexandria, VA)
- "Developing New Standards of Identity," Institute of Food Technologists Food Policy Impact Conference; February 11, 2020 (Washington, DC)
- "Trends in Animal Food Litigation," Food & Drug Law Institute (FDLI) Annual Conference; May 3, 2018 (Washington, DC)
- "Nutritional Labeling Challenges: Cutting Time to Market and Speeding Compliance Activities," Q1 Productions Food Labeling Conference; January 29, 2018 (Arlington, VA)
- "FSMA's Foreign Supplier Verification Program and VQIP - Are You Ready?" American Association of Exporters and Importers (AAEI) Healthcare Industries Committee (HIC) and Regulated Industries Committee (RIC) Seminar; April 27, 2017 (Washington, DC)

Emily has also spoken on cannabis-related topics, including the following presentations:

- "Legal & Regulatory Update: Recent Developments Affecting the Hemp and CBD Industries," Texas Hemp Convention; January 30, 2020 (Dallas, TX)
- "Beyond the High: A Global View on Brand Considerations for Cannabis," 2019 ABA-IPL Annual Meeting and Intellectual Property Law Conference; April 11, 2019 (Arlington, VA)
- "Emerging Regulatory Challenges & Considerations for Cannabis Promotional Products," PPAI Product Responsibility Summit, September 18, 2018 (Alexandria, VA)
- "Making Health Claims under FDA Scrutiny," National Cannabis Industry Association Cannabis Business Summit, July 25, 2018 (San Jose, CA)
- "Marijuana Technology for Medical Purposes," International Bar Association World Life Sciences Conference; June 1, 2018 (Boston, MA)
- "Deep Dive: Regulations and Compliance Tips Tactics," Marijuana Business Conference; November 17, 2017 (Las Vegas, NV)
- "The Business of Hemp Forum: Legal & Regulatory Update," Marijuana Business Conference; November 14, 2017 (Las Vegas, NV)
- "The *Other* Feds: Worried about the DEA or the DOJ? What about the FDA, FTC, and Health Canada?" National Cannabis Bar Association (NCBA) Cannabis Law Institute; July 29, 2017 (Glendale, CO)
- "Regulation of Cannabis in FDA-Regulated Products," Food & Drug Law Institute (FDLI); July 19, 2017 (Webinar)
- "The Perils of Rescheduling and FDA Regulation," Marijuana Business Conference & Expo; May 18, 2017 (National Harbor, MD)
- "Regulation of Cannabis in FDA-Regulated Products," Food & Drug Law Institute (FDLI) Annual Conference; May 5, 2017 (Washington, DC)
- "What's FDA Got to Do With It? Understanding the Intersection of FDA Regulation and the Cannabis Industry," Cannabis World Business Congress & Expo; September 8, 2016 (Los Angeles, CA)

Recognitions

Emily was recognized in the 2024 Edition of Best Lawyers: Ones to Watch.

Bar Admissions

California

District of Columbia