EXHIBIT B

Practice Areas

Cosmetics
Dietary Supplements
Tobacco & Nicotine Products
Food & Beverages
Drugs & Biologics
Medical Devices
Cannabis
Advertising
Compliance & Enforcement
Transactions & Due Diligence
Consumer Products

Education

J.D., Harvard Law School (cum laude)
B.A., Emory University (magna cum laude, phi beta kappa)
Hebrew University, Jerusalem

Overview

Stacy Ehrlich draws on more than 25 years of experience to counsel her clients in the pharmaceutical, food, dietary supplement, tobacco, cosmetic, and medical device industries on regulatory and advertising law matters. In particular, Stacy provides practical, creative, and strategic advice to help clients achieve their business goals in compliance with laws and regulations implemented and enforced by the U.S. Food and Drug Administration (FDA), U.S. Department of Agriculture (USDA), Federal Trade Commission (FTC), Consumer Product Safety Commission (CPSC), and related federal, state, and local agencies. These matters include rulemaking and guidance development proceedings, premarket submissions, enforcement actions, legal challenges to agency action, advertising and labeling copy and claim substantiation, and expert due diligence.

Stacy serves as outside counsel for the Coalition of Independent Tobacco Manufacturers of America (CITMA) and the Coalition of Manufacturers of Smoking Alternatives (CMSA) and has been extensively involved FDA's regulation of tobacco and nicotine products since the early legislative process of the Family

Clerkships

Law Clerk for the Honorable Alexander B. Denson, United States District Court of the Eastern District of North Carolina

Admissions

Washington, D.C.

A prolific author and speaker, Stacy is frequently called upon to educate others on topics of food and drug law, including OTC drug, cosmetic, and dietary supplement labeling and marketing and nicotine and tobacco product regulation and enforcement. She has also regularly authored chapters in the Food and Drug Law Institute (FDLI) publications, Food and Drug Law & Regulation, How to Work with the FDA, and Top 20 Food and Drug Cases & Cases to Watch.

Stacy has served on the Board of Directors of FDLI and has consistently been recognized for excellence in FDA Law by The Best Lawyers in America© and Super Lawyers©.

Prior to joining KKB, Stacy clerked for the Honorable Alexander B. Denson in the United States District Court of the Eastern District of North Carolina and practiced food and drug law at a large DC-based international law firm.

Experience

Representative experience:

- Assisted clients with obtaining FDA marketing authorization for tobacco products, medical devices, and drugs.
- Advised clients regarding labeling and marketing materials for cosmetics, tobacco products, over-the-counter drugs, foods, and dietary supplements.
- Assisted clients with responses to FDA warning letters and 483 notices of inspectional observations.
- Submitted comments to FDA rulemaking and guidance document dockets.

- Conducted FDA expert due diligence review for corporate transactions.
- Worked on an emergency use authorization (EUA) for a COVID-19-related product.
- Advised clients regarding the marketing of hand sanitizers and masks during the COVID-19 pandemic.
- Assisted clients with prescription-to-over-the-counter switch applications.
- Outside counsel to a tobacco industry trade association.

Publications & Speaking Engagements

Recent Publications

- "U.S. FDA and the Products it Regulates," Co-Author, Kirk-Othmer Encyclopedia (2019).
- "Cigar Association of America et al. v. FDA et al.," Co-Author, FDLI Top Food and Drug Cases, 2018, & Cases to Watch, 2019 (2019).
- "JUUL in Schools: Can FDA Close the Youth On-Ramp While Still Maintaining the Off-Ramp for Adult Smokers?," FDLI Update Magazine, Oct. 2018.

Recent Speaking Engagements

- Closing panel, Speaker. Global Tobacco & Nicotine Forum (GTNF) 2020, September 24, 2020.
- "Premarket Tobacco Product Applications (PMTAs) and the Impending Deadline," Moderator. FDLI webinar, June 24, 2020.
- "Nicotine: What it Is, What it Does, and How to Effectively Communicate this Information to the Public," Moderator. FDLI webinar, Feb. 18, 2020.

- "The Looming Premarket Submission Deadline for Deemed Tobacco Products: The Road Ahead," Moderator. FDLI Enforcement, Litigation, and Compliance Conference, Dec. 11, 2019 .
- "Ongoing Litigation – Updates & Debrief," Panelist. ENDS US 2019 | Exploring the Electronic Nicotine Delivery Systems Industry, Dec. 10, 2019.
- "Risk Communication to Adults: How Should Relative Risk Be Conveyed?," Moderator. Tobacco and Nicotine Products Regulation and Policy Conference, Oct. 24, 2019.
- "The Elephant in the Room: Tobacco-Free Nicotine," Speaker. Vapor Technology Association Annual Conference, Sept. 16, 2019.
- "Electronic Nicotine Delivery Systems: Regulation to Prevent Youth Initiation and Use," Moderator. FDLI Annual Conference: Exploring Advanced Topics in Food and Drug Law, May 3, 2019.
- "FDA's regulatory approach to addressing youth appeal and access: How should FDA close the on-ramp for youth while maintaining the off-ramp for adult smokers?," Panelist. The E-Cigarette Summit: Science, Regulation & Public Health, April 29, 2019.
- "Tobacco Enforcement Challenges and Recent Actions," Moderator. FDLI Enforcement, Litigation, and Compliance Conference: For the Drug, Device, Food, and Tobacco Industries, Dec. 12, 2018.
- "Risk Communications: Educating the Public About Harm Reduction," Moderator. FDLI Tobacco Products Regulation and Policy Conference, Oct. 26, 2018.

Insights

FDA Issues Five More Warning Letters to Marketers of CBD-Containing Products - December 24, 2020

DOCKET ALARM

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