Jae Kim

Associate

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Jae Kim is an associate in DLA Piper's FDA Regulatory Group, and advises clients in the life sciences, food and beverage, hemp and CBD, and consumer products industries.

Jae provides regulatory compliance and risk management advice to companies with products and operations subject to regulation by FDA, USDA, TTB, DEA, and FTC, as well as state regulatory authorities. Her broad regulatory practice encompasses medical devices, drugs (prescription and OTC), dietary supplements, food and beverage, alcohol, hemp and CBD products, and cosmetics.

As part of her regulatory practice, she regularly counsels clients on regulatory issues that arise throughout the product life cycle, including product development and approval strategy, current good manufacturing practices (cGMPs), state and federal licensing and registration, labeling, advertising and promotion, inspections, agreements pertaining to quality and regulatory issues, recall management, and regulatory enforcement actions.

Jae has extensive experience in conducting regulatory due diligence on behalf of companies seeking to acquire or invest in companies with a portfolio of regulated products. She also has experience in providing strategic regulatory advice and counseling for companies facing internal investigations, litigation, and arbitrations.

- Litigation, Arbitration and Investigations
- Product Liability, Mass Torts and Product Stewardship
- Regulatory and Government Affairs
- FDA

- Life Sciences
- Healthcare

Korean

Jae has also advised multinational and start-up companies on navigating federal and state COVID-19 requirements, including FDA's Emergency Use Authorization (EUA) process and enforcement discretion policies for personal protective equipment (such as face masks, face shields, gowns and gloves) as well as hand sanitizers and other medical products.

Jae serves on the Philadelphia office's Diversity & Inclusion Committee, and is the co-manager of Cultivate, a DLA Piper blog focused on the hemp and CBD industry. She is also actively involved in the regulatory community, and serves on the Food and Drug Law Institute (FDLI)'s Cannabis Products Committee and Webinar Committee, as well as the Membership Committee of Women in Bio - Philadelphia Metro chapter.

LANGUAGES SPOKEN

- Korean

EXPERIENCE

Jae's experience includes:

- Advising on product recall management and preparing recall-related submissions to FDA;
- Advising on FDA's adverse event reporting requirements;
- Counseling on state and federal permit and registration issues (FDA, DEA, TTB, CLIA, State Board of Pharmacy);
- Conducting legal review of labeling and marketing claims on foods and medical products based on FDA and FTC requirements;
- Drafting quality agreements involving contract manufacturers and raw material suppliers (cGMP/ISO);
- Providing strategic guidance on FDA's premarket approval or clearance process, including assessment of applicable product classification;
- Preparing responses to FDA Form 483 observations;
- Coordinating regulatory advice from counsel in Canada, Europe, Asia, and Latin America for clients with regulated products in multiple ex-U.S. jurisdictions; and
- Significant experience in conducting FDA/DEA/USDA regulatory due diligence in transactions on behalf of clients in corporate transactions involving regulated products.

CREDENTIALS

Admissions

- New Jersey
- Pennsylvania

Prior Experience

Jae worked as a summer law clerk and a summer associate at the Philadelphia office of DLA Piper.

Education

- J.D., University of Notre Dame Law School
  - Editor in Chief, *Notre Dame Journal of Law, Ethics & Public Policy*
  - Notre Dame Moot Court Board
- B.A., Johns Hopkins University

Courts

- United States District Court for the District of New Jersey
- United States District Court for the Eastern District of Pennsylvania

Memberships

Jae serves on the Young Lawyers Editorial Board of *The Legal Intelligencer*, the oldest law journal in the United States.

INSIGHTS

Publications

Compliance tips for marketing health benefits in alcohol

19 October 2021
As companies craft their marketing strategies around these alcohol products, they may wish to consider the impact of product classification on their claims.

The US Hemp Production Handbook

4 November 2020
A concise, high-level overview for businesses that are currently or are considering operating in this growing market.

Food and beverage COVID-19 regulatory updates

4 June 2020
Ongoing commentary and guidance from US regulators.

Food delivery fee disclosures and caps in the wake of COVID-19 pandemic

26 May 2020
As a result of customers' increased reliance on third-party food delivery services precipitated by social distancing measures and compliance with local stay at home orders, cities have begun to take note of the fees charged by third-party delivery service providers, often with disparate impact on restaurant companies of varying sizes and negotiating power.

- Co-Author, "Cos. Must Heed FDA Warning On Hand Sanitizers," *Law 360*, (August 2020)
- Co-author, "Get Ready For Digital Health Product Liability Cases," *Law360* (July 2018)
- Co-author, "Product Liability Implications in the Digital Health Industry," *Health Transformer* (November 2017)
- Co-author, "Promotion of Precision Medicine Under Imprecise Rules," *FDLI Update* (2016)
- Co-author, "Public Disclosure Bar Prohibits "Bounty-Hunting" Relators From Filing Duplicative FCA Claims," *DLA Piper Litigation Alert* (January 2016)

Events

Upcoming

Legal and Practical Issues in Cannabis Regulation

24-25 May 2022
Webinar

NEWS

DLA Piper names lawyers to Leadership Council on Legal Diversity 2022 Fellows and Pathfinders programs

10 March 2022
DLA Piper is pleased to announce that the firm has selected partner Rishi Sodhi to participate in the Leadership Council on Legal

Diversity's (LCLD) 2022 Fellows Program and has selected associates Ashley Bailey-Chang and Jae Kim to participate in the LCLD 2022 Pathfinders Program.