



Brian P. Waldman

PARTNER

Brian is a nationally recognized food, drug, and advertising advisor for companies in the life sciences industry.



Industries

Consumer Products
Life Sciences

Practices

Advertising & Promotions
Food, Drug, Medical Device & Cosmetic

International

Europe

Education

University of California, Los Angeles JD, 1992
University of Chicago MBA, with honors, 1987
University of Chicago BA, Phi Beta Kappa, 1986

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Skilled at developing strategies for introducing new products and ensuring post-market compliance, Brian works with companies in the pharmaceutical, medical device, food, dietary supplement, and cosmetic space. In recognizing Brian as one of the top lawyers in the country, *Chambers USA* reported that he stands out for his "great business sense."

Brian serves as a member of Arent Fox's Executive Committee, co-manager of the firm's Regulatory Department, and a partner in the Food, Drug, Medical Device & Agriculture group.

Client Work

Brian advises companies on a broad range of legal and regulatory issues throughout all phases of a product's life cycle, including:

- (i) developing appropriate strategies for the introduction of new ingredients and finished products,
- (ii) coordinating pre-market safety, efficacy, and claims evaluations,
- (iii) preparing FDA-related applications and notifications,
- (iv) designing compliant and effective labeling, advertising, and promotional materials, as well as educational materials,
- (v) ensuring post-marketing regulatory compliance, including compliance with adverse event reporting requirements and limitations on off-label promotion, and
- (vi) responding to threatened enforcement action and litigation.

As part of this work, Brian coordinates efforts between product developers, contract research organizations, site management organizations, institutional review boards, investigators, and the FDA.

Much of Brian's practice involves crisis management support. Brian assists clients in preparing for and during government investigations, as well as in evaluating and responding to adverse product information. He has coordinated numerous recalls, market withdrawals, and other product corrective actions.

Brian conducts regulatory compliance audits to ensure that both product manufacturers and distributors are in full compliance with applicable laws and regulations. Further, he has drafted proposed federal and state legislation in support of the interests of manufacturers and distributors and represented these interests before legislators and regulators.

Brian works extensively with attorneys in the firm's Health Care, Intellectual Property, and Corporate Transactional practices. He has negotiated numerous licensing, supply, and distribution agreements, conducted numerous due diligence audits of acquisition targets, prepared regulatory compliance opinions in support of public offerings, and supported food and drug-related litigation.

Publications, Presentations & Recognitions

Brian recently co-wrote a chapter on dietary supplements in the Food and Drug Law Institute's "Food and Drug Law and Regulation." He also co-wrote an article titled "Cosmeceuticals: The Legal Problem and Feasible Solutions," published in *The Food, Drug, Cosmetic, and Medical Device Law Digest*. Brian frequently lectures on food and drug approval and regulatory compliance issues for the Food and Drug Law Institute, the Biotechnology Industry Organization, the Center for Professional Advancement, the American Conference Institute, and other seminar sponsors.

Brian has been recognized as a Leading Lawyer by *Chambers USA* in the area of Food & Beverages and is annually rated among the *Best Lawyers in America*.

Bar Admissions

California

District of Columbia