

Labeling, Advertising, and Promotion

Our regulatory compliance practice for the labeling, marketing and advertising of drugs, medical devices, human and animal foods, dietary supplements, cosmetics, and other consumer products is deep and long-standing. Our extensive experience with both U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC) regulatory and enforcement policies allows us to effectively anticipate and mitigate legal risks across the multi-faceted aspects of a marketing campaign. We regularly counsel clients on the permissible boundaries of promotional claims and marketing activities for specific products, represent companies who have received FDA warning or untitled letters, and FTC civil investigative demands (CIDs) and negotiate for the termination of investigations or limitations to proposed consent decrees, involving criminal enforcement actions arising from the promotion of prescription and over the counter (OTC) drugs, dietary supplements, and medical devices.

We also provide risk assessments for proposed promotional strategies, and represent clients responding to FTC CIDs, National Advertising Division inquiries, Lanham Act, and other disputes involving allegations of false or misleading advertising.

Key aspects of our work include the following:

- Providing legal counsel on the substantiation standards for health-related, efficacy, and safety claims;
- Reviewing advertising claim substantiation to help ensure that the type, quantity, and quality of evidence meets the standard expected by regulators and courts;
- Developing legal strategies to defend clients in government investigations and competitor challenges, as well as initiate legal challenges against our client's competitors for false and misleading advertising;
- Advising on appropriate label and marketing claims that meet FDA regulatory requirements for a product category; and
- Counseling clients on a broad range of marketing dissemination strategies, including through endorsements and testimonials, and social media.

Contact Us

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