Hogan Lovells

Medical Foods and Dietary Supplements

Medical foods and dietary supplements are technically foods, not drugs. But different rules around safety, labeling, and manufacturing apply. It can be challenging to keep up.

Certain foods and ingredients have been shown to be effective in managing disease and health related conditions and supporting overall well-being. We advise clients on the legal parameters impacting foods and supplements used for managing health conditions.

Our food lawyers can guide you whether you manufacture medical foods or dietary supplement ingredients or use them in products. We help assess the regulatory status, safety, and compliance of your products, addressing any problems that may arise along the way. We routinely counsel clients on product classification issues, legal requirements for product safety, and claims made in labeling and advertising.

Our understanding of the legal requirements and underlying science allows us to help companies determine whether they should position their product as a medical food, food for special dietary use, conventional food, or a dietary supplement. We also assist clients in developing the data that are needed to substantiate claims and support the regulatory classification of the product.

Our extensive experience extends to frequent counseling on issues arising under the Dietary Supplement Health and Education Act, the Federal Trade Commission Act, and laws of interest to dietary supplement companies. We closely follow

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Practices

Food Law

the FDA's development of supplement regulations and policies as well as enforcement trends.

Medical foods are a unique subset of foods that are specifically designed to meet the unique nutritional requirements that may exist for managing a disease or health related condition. Medical foods must be administered under medical supervision and the nutrients cannot be achieved through normal modification of the diet.

Representative experience

Represented dietary supplement companies in successfully responding to FTC inquiries on nutrition-related claims, resulting in closure of the investigations or consent orders to resolve threatened enforcement.

Assisted clients in developing health claim petitions that would authorize the use of various health claims on dietary supplements and conventional foods.

Successfully represented several importers of dietary supplements and other products in obtaining release of FDA-detained shipments, enabling the importation of commodities and minimizing marketing disruptions.

Conducted due diligence investigations for companies subject to takeover or merger activity, assisting with identifying serious regulatory deficiencies to stop a company from acquiring another's problems.

For dietary supplement companies planning to undertake clinical research, we are providing counsel as to whether Investigational New Drug (IND) applications are required or prudent.

Counseled dietary supplement and other companies on product classification issues and the regulatory pathway (e.g., food, dietary supplement, medical food, drug) most likely to meet desired objectives.

Helped clients assess the status of proposed claims and ingredients (especially new dietary ingredients) and prepare any necessary notifications to the FDA.

Latest thinking and events

Webinar

Influencer Snapshot webinar series: Influencers around the world

News

California's OEHHA releases draft report questioning the safety of FDA approved certified colors

Webinar

International Dairy Foods Association's Regulatory RoundUP conference

Webinar

Food Labeling & Immune Support Claims in the Time of Coronavirus

News

National Advertising Division Issues Decision on "100% Natural," Satiety, and Curbing Cravings Claims

Hogan Lovells Publications

Lessons learned from post-9/11 and anthrax experiences to be applied to COVID-19 in the food industry