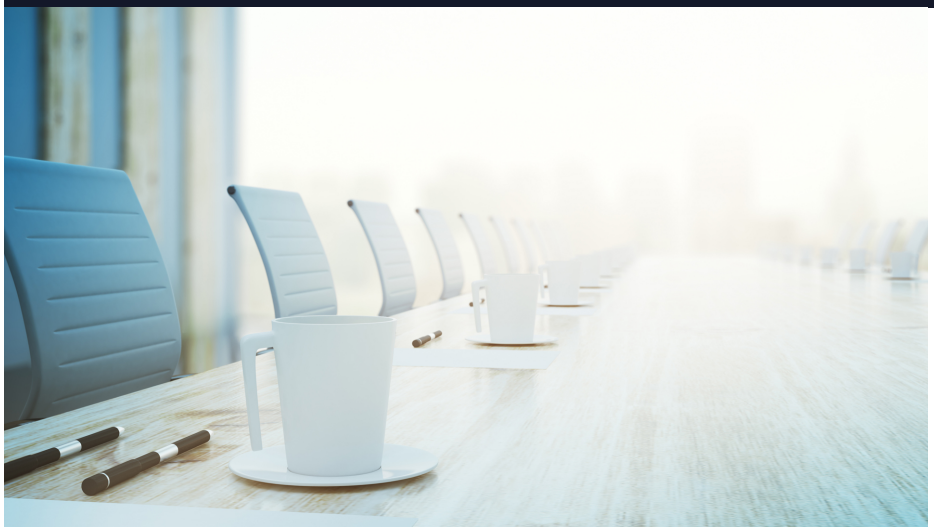
BARNES & THORNBURG LLP



FOOD, DRUG AND DEVICE LAW

Open For Business

Barnes & Thornburg's Food, Drug and Device Law practice group helps pharmaceutical, biotechnology, medical device, diagnostic, food, dietary supplement and cosmetic companies, as well as other healthcare entities, throughout the product lifecycle, from concept, development and approval to manufacturing, marketing, ongoing compliance, investigation, enforcement actions and litigation.

We advise clients on the ever-evolving laws and FDA regulations that govern their products and components. Moreover, we have the government experience and industry knowledge necessary to develop innovative strategies to handle the regulatory challenges that these companies face.

Barnes & Thornburg LLP regularly assists clients with issues in a number of FDA-related areas, including:

Medical Devices

Many new medical devices must be reviewed by the FDA before they can be marketed. Before FDA authorizes marketing, scientists at the FDA review the manufacturer's data from investigational studies to see if the product does what it claims to do effectively and does not present any unreasonable risks to the patient. Our FDA group is available to assist with classification of devices; pre-market notifications (510(k)s) and pre-market approvals (PMAs); combination products; product liability issues for finished device manufacturers and component suppliers; Good Manufacturing Practices/Quality System regulations; investigations; advertising and other matters.

Drugs

Why Barnes & Thornburg?

Finding new ways to help clients identify solutions and new business opportunities, across industries, is at our core. We are, at times, more than lawyers, we are advisers bringing new ideas to light. We understand what keeps you up at night and work collaboratively to find practical and creative solutions, at the heart of business.

RELATED PRACTICES

Corporate

Therapeutic drug development is accomplished through a complex series of interactions among government regulators, medical professionals and the pharmaceutical industry. Our FDA attorneys can provide the experience and sophisticated legal skills necessary to successfully and strategically navigate these multi-faceted exchanges. Specifically, we counsel clients on many aspects of human and animal drug requirements, including labeling; combination products; over-the-counter drug monograph compliance; GMPs; and advertising.

Foods

All food products must be labeled in a manner that complies with the laws established by the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Fair Packaging and Labeling Act (FPLA), and the Nutrition Labeling and Education Act (NLEA). Attorneys in our Food, Drug & Device group can assist clients with matters related to labeling (e.g. health, nutrient content and structure/function claims, allergens, Nutrition Facts); ingredients (e.g. generally recognized as safe (GRAS) self-affirmations, food additive petitions, new dietary ingredients); Bioterrorism and Food Safety Modernization Acts compliance; Good Manufacturing Practices (GMPs); inspections (international, federal, state and local); import/export; recalls; product liability; and advertising (e.g. weight management, children, competitive).

Dietary Supplements

The Dietary Supplement Health and Education Act of 1994 (DSHEA) classifies a dietary supplement as -a product taken by the mouth that contains a -dietary ingredient- intended to supplement the diet.- These products are considered a subsection under the general category of -foods- and must be clearly labeled as such. In addition, the organizations responsible for the product are also liable for determining the safety of the supplements, as well as substantiating any representations or claims made about their products with competent and reliable scientific evidence.

Our attorneys assist clients with dietary supplement-related issues including labeling (e.g. health, nutrient content and structure/function claims, allergens, Supplement Facts, analysis of scientific substantiation); ingredients (including new dietary ingredient submissions); Bioterrorism Act compliance; GMPs; inspections (international, federal, state and local); import/export; recalls; product liability; advertising (e.g. weight management, children, competitive); and adverse event reporting.

Cosmetics

The regulations established by the FD&C Act and the FPLA are among the most important laws pertaining to cosmetics marketed in the U.S. Together, these laws establish the criteria for misbranded products, prohibit the marketing of adulterated or misbranded cosmetics in interstate commerce, and require an ingredient declaration so that consumers are able to make informed purchasing decisions. Moreover, the laws hold cosmetic firms responsible for substantiating the safety of their products and ingredients before introducing them to the market.

We are available to counsel and assist clients with cosmetic-related issues

such as labeling; ingredients; classification of combination products; GMPs; product liability; safety and efficacy testing of cosmetic ingredients; import/export; product recalls; and advertising (including endorsements and testimonials).

Practice Leaders

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