Buchanan Ingersoll & Rooney PC

FDA & BIOTECHNOLOGY – Foods & Medical Foods

Bringing Your Products Safely To Market

Under the Federal Food, Drug, and Cosmetic Act (FDCA), "food" is not just food – it includes conventional foods, food for special dietary use, medical food, infant formula, and dietary supplements. Each type of product is heavily regulated by the Food and Drug Administration (FDA). Manufacturers therefore need guidance to contend with these unique regulations. Our FDA & Biotechnology team is well-versed in each of these categories and is ready to assist your company in gaining approvals, bringing your products to market, and keeping them there.

How We Can Help You

We can advise product manufacturers located in the U.S. and abroad on all U.S. compliance issues. For international clients, this also includes issues related to importing your product into the U.S. Our work involves interacting not only with FDA, but also with the U.S. Department of Agriculture (USDA), the Federal Trade Commission (FTC), and U.S. Customs and Border Protection (CBP).

The Right Experience

Very few firms have the experience we can provide to steer you through the regulatory complexities, no matter what the food products category. Our team includes a former Associate Chief Counsel for Foods at the FDA and other attorneys with deep industry knowledge and experience. We have even helped the FDA establish its policy with regard to acceptable levels of risk for direct and indirect food additives and generally recognized as safe (GRAS) substances.

Guiding You through the Regulatory Maze

Your specific regulatory framework is largely determined by the claims you make about your products in labeling and promotional materials. We are well equipped to handle the regulatory challenges that you may face with all types of "food."

Conventional Foods. On both the ingredient side and the finished product side, we can anticipate and solve issues that may impact food manufacturers, including implementation of the Food Safety Modernization Act (FSMA) and requirements for nutrition facts labeling. The range of products we have worked with include dairy, fresh produce, juices and sports drinks, energy drinks, teas, condiments, baked goods, confectionary products, and more. From nutrition labeling requirements to state and FDA food facility inspections, enforcement actions, and more, we've got you covered.

Medical Foods. Because they are used to treat a medical disorder, medical foods can function more like drugs than conventional food products, adding to the regulatory complexity. We have worked with many medical foods manufacturers and are highly skilled in navigating the regulatory landscape of this increasingly important product sector. We can advise you on the regulatory differences between medical foods and dietary supplements to determine an appropriate product development and marketing strategy. We can counsel you on how to respond to FDA's evolving regulatory position regarding these products. And we can help you develop the clinical evidence needed to support marketing of medical foods.

Dietary Supplements and Foods for Special Dietary Uses. We have extensive experience working with manufacturers of dietary supplements such as vitamins and minerals on just about every issue they face, including claims substantiation. We can help you create expert panels to evaluate the GRAS status of a product and provide a risk assessment. We can identify ways to mitigate product liability risks. And we can advise you on insurance coverage and reimbursement issues for products that traverse the healthcare/nutrition boundary, such as prenatal vitamins.

ADVANCING OUR CLIENTS' GOALS

The Multi-Regulatory World of Beer

We have advised beer clients on various issues, including ingredient safety and adulteration; use of genetically modified yeasts in the manufacturing process; Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) label warning requirements; and Environmental Protection Agency (EPA) issues regarding the use of chlorofluorocarbons (CFCs) as a refrigerant.

FSMA's Impact on Leafy Greens

We have advised a food client about how the implementation of FSMA impacts its production of leafy greens. We reviewed the company's standard operating procedures, and identified areas that would benefit from additional processes and procedures.

Is it a Medical Food or a Dietary Supplement?

We have provided counsel to a foreign company about whether its US-marketed product is a medical food or a dietary supplement, including key distinctions between product categories, labeling requirements, and claims phrasing.