

# OUR PRACTICE

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## FDA Regulatory and Compliance

**The regulatory environment created by the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture, and the Federal Trade Commission is demanding, complex and wide-ranging. Baker Donelson's lawyers practice in the most dynamic areas of Food and Drug regulation, and have broad experience navigating those complexities. We take a creative approach, encouraging innovative solutions, but all based on in-depth knowledge of the issues, entities and rules and with a pragmatic, realistic application of that knowledge.**

We advise established and emerging manufacturers, processors, marketers and other supply chain contributors of foods, prescription and OTC drugs, biologics, medical devices, dietary supplements, cosmetic and personal care products, medical foods and combination products. The diverse range of activities with which we have assisted our clients includes regulatory strategies and compliance; advertising, labeling, promotion, and product claim support; protection of intellectual property; government and quasi-government enforcement actions; litigation and dispute assistance, and sophisticated due diligence investigations. Our attorneys also help clients navigate the patchwork of state regulations affecting their businesses.

We excel at assisting clients in moving from unknown or early development status to national or international prominence. Baker Donelson's dedicated team of Food and Drug attorneys are experienced in helping shape the financing and internal growth process that takes a company from a low revenue base to real economic and commercial strength. We have guided many clients along this road to success, especially in the product areas of OTC drugs, medical devices, dietary supplements and personal care products.

Our litigation team handles a wide variety of Food and Drug related disputes. We have extensive experience litigating regulatory challenges, both in administrative agencies and courts, as well as all manner of cases involving clients operating within the Food and Drug regime. Our team regularly represents clients in trials and appeals of government regulated matters nationwide. Because of our deep Food and Drug and trial expertise, our litigation team has had notable success in defending consumer class actions based on the various states' false and deceptive trade practice statutes, challenging labeling and advertising restrictions on First Amendment grounds, and challenging burdensome regulations pursuant to the Administrative Procedure Act, the Commerce Clause, and Preemption.

## Food, Drug and Device Practice Outside the United States

In today's global economy, successful businesses look beyond geographic borders to explore new markets and resources. Baker Donelson believes that our clients benefit most from first-hand, local representation of their business goals and needs, and has therefore worked to develop an extensive international network of contacts who are knowledgeable of their own country's regulatory agencies and rules. We have well-established, ongoing relationships with local law firms around the world, in locations as diverse as Brazil, Turkey, the Netherlands and Japan, and within our practice group we have professionals with fluency in several languages, including Mandarin Chinese.

By drawing on our international contacts and internal resources, we are able to advise and guide our clients on issues related to licensing, intellectual property and import/export requirements of key world markets.