

Food, Drug & Cosmetic

General Counsel and Litigation Counsel for Companies in the Food, Drug and Cosmetic Industries

Kaufman Dolowich understands the unique challenges facing companies in the food, drug and cosmetic industries because we have faced them ourselves, firsthand. We have significant experience representing companies of all sizes, including some of the world's largest personal care companies. Kaufman Dolowich has helped numerous clients navigate the myriad of complex and high-risk issues involved with manufacturing and distributing products. This includes all types of products regulated by the U.S. Food and Drug Administration (FDA), Federal Trade Commission (FTC), Consumer Safety Commission (CPSC), US Department of Agriculture (USDA), and regulations/laws such as Food Drug & Cosmetic Act, Fair Packaging and Labeling Act, Federal Trade Commission Act, FTC Green Guides, National Organic Program, California Organic Products Act, Prop 65, California Consumer Privacy Act, to name a few.

We serve many of our food, drug and cosmetic clients as outside general counsel (GC). However, we also provide ad hoc representation when this makes the most sense, and we serve as litigation counsel for both GC and non-GC clients. Contact us to speak with one of our attorneys and learn more about our services for companies that manufacture, sell and/or import:

- *Agriculture Products*
- *Alcoholic Beverages*
- *Biologics and Biotechnology*
- *Cannabis Products*
- *Cosmetics*
- *Dietary Supplements*
- *Foods*
- *Medical Devices*
- *Personal Care Products*
- *Prescription Drugs*
- *Over-the-Counter (OTC) Medications*
- *Pharmaceuticals*
- *Importers*
- *Other Products Regulated by the FDA*

General Counsel Services for Food, Drug and Cosmetic Businesses

Serving as outside general counsel affords the firm's attorneys the opportunity to get to know our clients' businesses in-depth and provide proactive legal advice and recommendations on an ongoing basis. Many of our clients prefer this model because of its comprehensiveness, and because it is the most cost-effective solution to their complex and constantly-evolving legal needs. As outside general counsel to companies on the food, drug and cosmetic industries, our services include:

Day-to-Day Legal Advice & Counsel

Executives of food, drug and cosmetic companies encounter legal issues on a day-to-day basis. As outside general counsel, Kaufman Dolowich is available to provide advice and counsel as needed. With deep experience in the food, drug and cosmetic industries, we bring substantial subject-matter knowledge to the table, and we are able to efficiently answer many questions immediately. When a

factual investigation or legal research is required, our lawyers draw upon their experience to provide insightful and actionable answers, as quickly as possible.

Formulation, Manufacturing & Safety

Our attorneys assist food, drug and cosmetic companies with all matters pertaining to the formulation of their products, which includes everything from intellectual property issues to the substantiation of safety claims regarding individual ingredients. We provide comprehensive legal guidance with regard to manufacturing practices, handling practices, quality control, inspections and other related matters as well.

Safety, of course, is a priority for all food, drug and cosmetic companies. Our attorneys are well-versed in both the legal requirements for safety as well as the practical and risk-related considerations involved in making decisions regarding safety-related matters. Thus, not only can we tell you what your company is legally required to do, but we can explain if and why it may be in your company's best interests to go above and beyond.

Labeling and Advertising

Labeling and advertising are two areas where food, drug and cosmetic companies can get into trouble if they are not careful. We assist our clients with all aspects of labeling and advertising law compliance, including with respect to label declarations, product names and identity, warnings, ingredient lists, nutrition information, claims of effectiveness, comparative advertising and other similar types of matters.

Our attorneys have particular experience in the field of organic products. Companies need to be careful when making claims regarding the organic nature of products and ingredients, and false claims can lead to problems with both consumers and regulators. This applies to environmental claims as well, and allegations of "greenwashing" can lead to both bad publicity and legal liability. Our lawyers know the rules inside and out, and we work with our clients to help them avoid false or misleading claims that could lead to exposure.

Intellectual Property

Intellectual property (IP) rights are essential to many aspects of our clients' businesses. We assist our clients with all IP-related matters, from trademark clearance and enforcement to patent registration and licensing. Protecting a company's IP rights and respecting third parties' IP rights are equally important, and we work with our clients to ensure that they know what they need to protect and what they need to do (or not do) in order to avoid infringement.

Regulatory Compliance

Establishing, maintaining and documenting regulatory compliance are key issues for food, drug and cosmetic companies. The FDA, the Federal Trade Commission (FTC), the Consumer Product Safety Commission (CPSC), and various other state and federal agencies scrutinize these companies' products, labels, advertising claims and more. When faced with regulatory scrutiny, companies need to be prepared to affirmatively demonstrate compliance. We work with our clients to ensure they remain compliant, and are prepared to prove compliance when required to do so.

From developing and implementing compliance programs to interfacing with regulatory authorities, we assist our food, drug and cosmetic clients with all aspects of regulatory compliance management. When necessary, Kaufman Dolowich also provides defense representation for regulatory audits, inspections and investigations.

Retail and Distribution Contracts

Kaufman Dolowich attorneys in our Food, Drug & Cosmetic Practice Group have negotiated distribution contracts with many of the largest retailers in the United States. Establishing and maintaining relationships with these companies requires a clear understanding of how they operate, what they are (and aren't) willing to accept, and what makes deals financially attractive. By negotiating in conjunction with our clients' sales teams, Kaufman Dolowich attorneys are able to leverage their knowledge from past deals, and they help ensure that our clients' sales teams don't inadvertently make costly mistakes.

We are able to assist with retail and distribution contracts with smaller vendors as well. We also have significant experience in the e-commerce arena, and we have helped many of our clients open overseas markets. As a result, regardless of whether you are trying to get your company's products on pharmacy shelves or sell them to a worldwide audience, we have the knowledge, insights and

capabilities your company needs to grow.

Other Contractual, Importation and Business Matters

At Kaufman Dolowich, we assist our GC clients with other contractual matters as needed, including everything from drafting warranties and guarantees to negotiating supply agreements and other commercial contracts to navigating complex importation requirements for food, drugs, cosmetics, beverages, alcohol and other consumer products. Many of our clients have contract-related needs on a daily basis, and we work with these clients to implement protocols for meeting their needs and managing their contracts effectively.

From forming new subsidiaries to drafting employment policies and procedures, we assist our clients with general business matters as well. Here, too, we focus on providing proactive advice and actionable recommendations that keep our clients moving forward rather than bogging them down.

Litigation in the Food, Drug & Cosmetic Industries

It is not uncommon for companies in the food, drug and cosmetic industries to encounter litigation. These companies face litigation risks on various fronts; and, ultimately, there is only so much they can do to prevent lawsuits from being filed.

Food, drug and cosmetic companies must also be prepared to take legal action when necessary. Whether to protect their IP assets or enforce their contractual rights, there are various reasons why companies may need to institute litigation. We represent our clients as both plaintiff's counsel and defense counsel, and we have extensive experience in the areas of:

- Regulatory Litigation – Defense of companies in regulatory litigation involving the FDA, FTC, CPSC, and other governmental authorities.
- Voluntary and Mandatory Recalls – Defense of companies facing litigation arising out of recalls and alleged failures to recall in state and federal court.
- Consumer Litigation – We defend companies in consumer litigation involving product liability claims, false advertising claims and other claims for damages.
- Class Action Litigation – Defense of class action lawsuits, multi-district litigation (MDL), and other group and representative action cases nationwide.
- Commercial Litigation – Defense of lawsuits filed by competitors, vendors, distributors and other commercial parties, as well as pursuing commercial litigation in state and federal court.
- Employment Litigation – Defense and assertion of claims in litigation involving contractual and at-will employees.

Who We Serve

Our experienced team works with large and mid-size companies who are navigating the complex legal and regulatory landscape. Our attorneys provide solutions that are tailored to the unique demands of your business and operations.

We are committed to promoting diversity in all aspects of our practice. Kaufman Dolowich is one of only 100 law firms to achieve Mansfield 3.0 Certification in 2020, and we are in the process of securing Mansfield 4.0 Certification for 2021. We take pride in working with like-minded companies, and we are happy to share any additional information you would like about our firm's diversity and inclusion initiatives.

Speak with an Attorney in Our Food, Drug & Cosmetic Practice Group to Learn More

If you would like to know more about how we help companies in the food, drug and cosmetic industries, we encourage you to speak with an attorney in Kaufman Dolowich's Food, Drug & Cosmetic Practice Group. Please contact Practice Group Leader Christopher

Nucifora.

Food, Drug & Cosmetic's Leaders

- Christopher Nucifora