

VENABLE_{LLP}

Official Legal and Regulatory Partner
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CALIFORNIA › DELAWARE › MARYLAND › NEW YORK › VIRGINIA › WASHINGTON, DC

Providing Full Legal Service to the Dietary Supplements, Cosmetics, and Functional Foods Industry

With decades of FDA and marketplace experience, Venable is one of America's best-known law firms, with a proven track record of serving the dietary supplement industry. At Venable, we are proud that our food, medical devices, and dietary supplement clients come to us to solve their most complex legal issues, relying not only on the knowledge and skills of our attorneys, but also on our unwavering commitment to outstanding service and valuable counsel. Our clients rely on Venable's broad capabilities and experience across an array of disciplines, including: dietary supplement health and education; FTC and FDA regulations, advertising, marketing, labeling/packaging, competitor challenges, class action suits; state attorneys general investigations; intellectual property, patent, trademark, and copyright litigation; and international trade. We immerse ourselves in our clients' businesses so that we fully understand the context of their legal issues. By being fully aligned with their legal and business objectives, we deliver creative, integrated solutions that add value to our clients.

Selling the latest dietary supplement? Cosmetic or functional? We'll help you get it to market.

Food, drugs, cosmetics, and medical devices are highly regulated by the Food and Drug Administration (FDA). And they face fierce competition for the attention of consumers. The scrutiny by the FDA and the battle in the marketplace demand courage, imagination, and extraordinary technical and legal skills.

Regulated consumer products constitute a huge and burgeoning market. Dietary supplements and functional foods alone account for more than \$15 billion per year in sales. Once an FDA-regulated product makes it to market, it becomes one of the most closely regulated products in the world—subject to a diverse set of regulatory concerns. You're in an exciting and challenging industry—and Venable is, too.

We help clients at every step of the product life cycle—from product development and regulatory approval/clearance to advertising, marketing, and distribution.

Food and Drug Administration

Federal Trade Commission

REGULATORY CONCERNS	PRODUCT CLAIMS	ADVERTISING / DISSEMINATION
FDA Approval Needed?	Substantiation	Assess Scientific Burden
Packaging / Labeling	Risk Assessment	Define Ad Claims
Regulatory Enforcement Action		Litigation / NAD / ERSP
		Respond to Civil Litigation

Representative matters:

- › Successfully representing clients in challenging agency decisions involving labeling, advertising, approval, and licensing;
- › Successfully representing clients in litigation involving FDA; and
- › Successfully defending against an FTC challenge involving a client accused of making false claims by discrediting the FTC's scientific basis for the challenge.

Resources at Every Step—From Idea to Store

Your marketing campaign

Success often requires aggressive marketing, which can raise legal challenges—starting with the claims you make. Venable attorneys can help you assess the risks your campaign may entail—including claims addressed in the Dietary Supplement Health and Education Act and the Nutrition Labeling and Education Act. We also help assess the proof required for product claims under FTC regulations and what you can say (and cannot say) about competing products. We routinely conduct ingredient reviews and product safety assessments, and evaluate food contact ingredients.

We work closely with Venable's Marketing and Advertising attorneys to ensure that your message will reach its audience with the impact you desire, without running afoul of regulatory issues.

Your intellectual property

Protecting your patents, trade secrets, trademarks, and copyrights is critical throughout the process. Our attorneys are leaders in these areas. We structure and negotiate licenses, research contracts, and technology transfer agreements. And we know how to protect your product and preserve your ability to market and profit from it in a competitive environment.

Your regulators and your competitors

You may need to assert your interests aggressively—by challenging the regulators or challenging your competitors. We are leaders in advocacy before the FDA and the FTC, and in bringing them to court when necessary.

We also know how to address bad behavior on the part of your competitors through challenges to false advertising under the Lanham Act and other state and federal statutes, or before self-regulatory bodies, such as the NAD or ERSP.

Your challengers

It happens: someone challenges your product or your advertising. It could come from an individual or a class action suit. Or it could be a government agency. We have years of experience in dealing with:

- › Adverse Event Reports;
- › Challenges before the Federal Trade Commission (FTC);
- › Competitor challenges to advertising in proceedings before the National Advertising Division (NAD) of the Council of Better Business Bureaus or the Electronic Retailing Self-Regulation Program (ERSP);
- › Current good manufacturing practices;
- › False advertising (Lanham Act) litigation;
- › Food additives;
- › Food contact substances;
- › FDA import detentions;
- › FDA inspections;
- › FDA warning letters;
- › Patent, trademark, and copyright litigation;
- › Proposition 65 litigation;
- › State attorneys general; and
- › Other challenges faced by product developers and manufacturers.

Your Venable team's approach

Venable's approach to anticipating and solving problems often includes detailed client counseling on regulatory compliance, petitioning and negotiating with agency officials, advocating for legislation, and, where necessary, litigating aggressively and effectively.

Advertising and Marketing

Developing your brand required years of effort and substantial resources. Whether you are defending your market-leader status or you are a number two or three “trying harder,” Venable’s advertising lawyers are dependable partners who know how to help protect and grow your valuable brand.

We represent 10 of the top 20 largest national advertisers. Our lawyers know how to keep you out of the regulatory eye, mend a broken compliance program, or help navigate the difficult choices that come with balancing risk and reward. Our advice is far from theoretical. We provide practical answers based on our understanding of your business so that you can make informed, real-time decisions.

In a world where new avenues of advertising and promotion seem to spring up overnight, we have the depth to keep you fully informed and well advised in all areas. Whether it be social media, sweepstakes, green marketing, gift cards, affiliate marketing product placement, or traditional television advertising, we have lawyers who provide counsel in each of these areas on a daily basis.

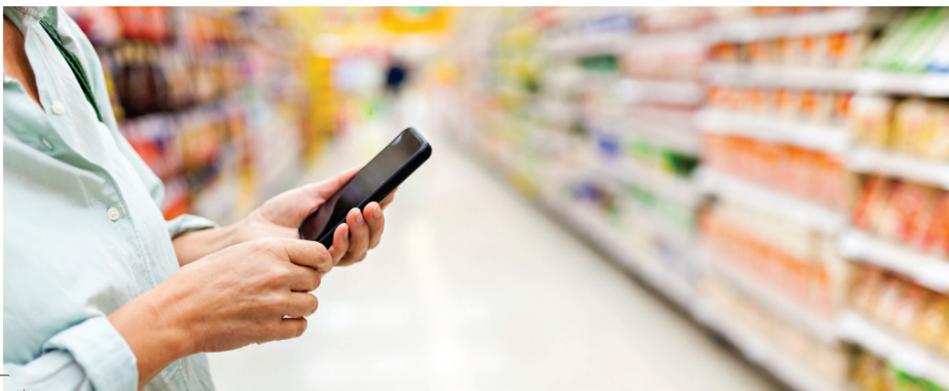
It is an unfortunate reality that one advertising problem can give rise to a host of others. A self-regulatory proceeding can lead to class action litigation or a class action can spawn multiple inquiries by state attorneys general. We believe a few hours of prevention are worth perhaps thousands of hours of a cure. This is why we put such emphasis on providing proactive counseling to our clients. However, if needed, Venable also has the bench strength to represent clients in every type of contentious setting simultaneously in a first-rate and efficient, coordinated manner.

While we are zealous advocates for our clients, we also believe open lines of communication are the key to resolving differences. We frequently collaborate with our regulatory and self-regulatory counterparts to provide insightful commentary on industry issues at conferences and webinars and in publications. These close working relationships help us get to know better the agencies regulating our clients and help build the relationships that can be critical to resolving enforcement actions amicably.

We advise some of America’s most iconic and beloved brand marketers, including leading companies in areas such as banking, breakfast foods, consumer packaged goods, dairy, hospitality, retail sales, telecommunications, toys, and travel.

Representative Matters:

- ▶ Providing advertising counsel to a leading national retailer. This engagement has included handling several FTC matters involving pricing issues, green claims, comparative performance claims, and textile act issues.
- ▶ Supplying comprehensive regulatory compliance counseling to one of the largest food companies in the United States. This includes guidance on claim substantiation, advertising to children, food marketing and packaging, sweepstakes and promotions, coupons and rebates, social media marketing, and privacy/data security matters.
- ▶ Performing a comprehensive assessment and update of a Fortune 500 diversified financial service company’s regulatory database to ensure that all future advertising and marketing practices were compliant with federal and state regulations and the conditions of a Consumer Financial Protection Bureau consent order.
- ▶ Advising a leading consumer electronics company on the global launch of its latest mobile handset. This engagement included compliance advice for on-line and off-line marketing in the United States, as well as coordination of local counsel in jurisdictions around the world.



Class Action Litigation

Class action lawsuits against advertisers and marketers are on the rise and they pose significant threats to their brands and their businesses. Successfully defending these cases requires mastery of the issues and complexities that are unique to class action litigation, as well as the procedural nuances of courts and jurisdictions around the country.

Venable is widely recognized as one of the nation's most highly regarded advertising and marketing law practices. We defend clients against class action claims alleging violation of state and federal deceptive trade practices, false advertising, unfair competition and other consumer protection statutes. Our experience includes achieving precedent-setting U.S. Supreme Court victories, acting in relation to federal appellate decisions, and defending class actions in state and federal court.

In addition, we frequently defend clients against false advertising claims before self-regulatory bodies such as the National Advertising Division (NAD). Venable's experience handling consumer class actions, Lanham Act jury trials, securing federal district court victories against government regulators, and staving off advertising-related investigations from the Federal Trade Commission (FTC) sets our firm apart from its competitors. Over the years we have prevailed in some of the toughest advertising-related litigation to go to trial.

Our experience in the courtroom, close ties to federal and state regulatory agencies, intimate understanding of industry self-regulatory bodies, and geographic reach are the primary reasons why clients turn to us for strategic counsel, advice, and legal representation.

If your advertising and marketing cannot stand up to a legal challenge, your product or service offering will most certainly be negatively impacted. Venable is a national leader in advertising and marketing litigation. When leading businesses need help defending against advertising class actions, they turn to us. Over the past year, Venable has defended against more than a dozen class action cases. Below is a description of some of our current and recently concluded matters in this area. These matters highlight Venable's track record of success, our ingenuity, and our ability to find value for our clients, even in the face of daunting class action claims.

- › Venable recently secured dismissals, with prejudice, for its clients—manufacturers and retailers of dietary supplements, and certain of their officers and executives—in a putative class action filed in the Central District of California. Challenging the labeling of various testosterone-boosting nutritional supplements as unsupported by reliable scientific evidence, Plaintiffs alleged, among other claims, violations of the Racketeer Influenced and Corrupt Organizations Act (RICO), and California and New York consumer protection and false advertising statutes, and sought substantial class-wide monetary damages, punitive damages, and injunctive relief. In its motion to dismiss the individual defendants, Venable principally argued that the California federal court lacked personal jurisdiction over the officers and executives; the motion to dismiss by the corporate defendants argued that plaintiffs had failed to state any viable claim. The Court agreed, holding that it lacked either general or specific jurisdiction over the individuals, and that plaintiffs failed to state a claim against the corporate defendants because, among other things, the RICO claim lacked predicate fraudulent acts and that the purported expert report upon which Plaintiffs relied actually refuted the very claims asserted in the complaint. The Court thus granted both motions to dismiss without allowing Plaintiffs to attempt to replead their claims.



- › Venable represents multiple defendants who allegedly participated in a marketing campaign to promote the movie *Last Ounce of Courage*, via unlawful pre-recorded telephone calls to plaintiffs' residential telephone line, in violation of the Telephone Consumer Protection Act, 47 U.S.C. § 227. Plaintiffs sought to represent a class of consumers who received unsolicited, pre-recorded telephone calls promoting the movie. However, discovery proved that the only message plaintiffs received on their answering machine did not contain a commercial advertisement, and plaintiffs never heard anything about the movie. The court granted the motions to dismiss filed by Huckabee, Leininger, Mission City, and Courage 2012 and dismissed the complaint. The court found that plaintiffs lacked Article III standing to pursue the action because they never heard any commercial advertisement, and further held that plaintiffs were inadequate class representatives because they were subject to a unique defense.
- › Venable is defending a major producer of poultry products in putative consumer class action lawsuits pending in the District of New Jersey and a more recently filed identical case in the Middle District of Florida. Both lawsuits are being supported by the Humane Society of the United States, an animal rights organization in which the plaintiffs are members. The suits principally claim that the "Humanely Raised" labels on our clients' chicken products are false and deceptive. Venable succeeded in dismissing claims in the New Jersey action concerning our client's "Raised Cage Free" labels. The court in the New Jersey action has granted Venable's motion to bifurcate discovery, so that merits discovery will not occur unless and until a class is certified – a decision which may save our client hundreds of thousands of dollars in discovery costs.
- › In a case that garnered national media attention, Venable defended an ABA-accredited law school in a putative class action filed in New York State Supreme Court by three of the school's alumni. Plaintiffs alleged that the school published misleading statistical information regarding its graduates' employment rates and salaries, and claimed fraud, negligent misrepresentation, and violations of New York's consumer protection statute. As damages, plaintiffs sought disgorgement of all tuition paid by members of the putative class, which, if aggregated, would exceed hundreds of millions of dollars. Plaintiffs also sought an injunction that would affect future publication of the school's graduate employment statistics. In October 2011, Venable filed a motion to dismiss all of the claims against the law school, which prompted plaintiffs to amend their complaint. In December 2011, Venable moved to dismiss the amended complaint. On March 21, 2012, our motion to dismiss the amended complaint was granted in full. Among other things, the Court held that the alleged misstatements were not sufficiently material to support a cause of action, and that plaintiffs had not sufficiently pleaded causation and injury. In December 2012, New York's Appellate Division, First Department, affirmed the decision.

Our litigators have successfully resolved numerous complicated class actions for clients in the food, beverage, dietary supplements, manufacturing, pharmaceutical and life sciences, media and entertainment, and retail sectors.

Trademarks and Brand Protection

Protect Your Brand and Online Presence

The dietary supplement, cosmetics, and functional foods industries face a unique array of brand protection challenges. Counterfeiting or fraud in these industries not only negatively impacts a company's brand but, more importantly, has real-world consequences and often threatens the health and safety of consumers. Fraud in particular can result in a number of negative consequences, including:

- › Harm to Consumers
- › Loss of Goodwill
- › Price Erosion/Suppression
- › Brand Dilution
- › Consumer Confusion
- › Lost Profits
- › Lost Market Share
- › Lost Opportunities

Food fraud is occurring with greater frequency and often occurs in one of two scenarios. The first is when a contract manufacturer supplies you with an impure or substandard ingredient. In this case, you assume the risk associated with that ingredient. The second, and more common, scenario is when an unscrupulous competitor sells impure, substandard, or mislabeled products that compete with yours, and may look like or infringe your brand or products in some way.

While there is no “cookie cutter” solution to address these brand protection challenges, companies seeking to better protect their brands and consumers should consider the following proactive strategies and best practices in the development of an anti-counterfeiting and brand protection strategy tailored to meet their specific needs in the marketplace.

Best Practices

- Conduct an internal brand protection audit to assess how well your key brands and products are secured in terms of legal protection, including an assessment of contracts for management of supply chain and distribution channels.
- Register key intellectual property rights — combine and layer intellectual property rights where appropriate.
- Increase engagement and collaboration with industry, government, and nongovernmental organizations, including U.S. Customs & Border Protection.
- Routinely monitor unauthorized use of your brands and establish surveillance of your distribution channels.
- Work with legal counsel experienced in the handling and management of intellectual property and brand enforcement programs that reduce the impact of counterfeiting, fraud, or other infringing activities

About Venable's Trademark and Brand Protection Practice

Venable's trademark team — bolstered by five former USPTO trademark examiners and two former in-house counsel — has been a leader in trademark filings. The firm ranks in the top 20 law firms in terms of applications filed and registrations issued, based on annual rankings issued in 2007–2015, by *Trademark Insider/World Trademark Review*, and among the top 10 law firms by *Intellectual Property Today* in 2015. Venable's trademark practice is recognized in the *World Trademark Review 1000 — The World's Leading Trademark Professionals* among the top groups in the United States — DC Metro area.

Venable's Brand and Content Protection team has years of experience battling counterfeiting, piracy, and product diversion on a global scale. We use an innovative and proactive approach in working with our clients to develop effective brand protection programs that prevent or reduce the negative impact counterfeiting and IP theft have on your business.

Whether you seek to implement a global brand protection program or simply to pursue counterfeiters in a particular market, we design programs that are custom-tailored to meet your business objectives and address local nuances wherever you operate. We work seamlessly with a proven network of IP enforcement professionals around the world. Furthermore, we leverage our years of experience and breadth of global contacts to work efficiently with local government officials, and various international and regional IP enforcement and policy associations, to better protect our clients' valuable brands and IP rights.

Venable has a long history of working with regulatory and law enforcement agencies to address counterfeiting issues. Our team has well-established relationships with such agencies as the U.S. Customs and Border Protection, the National Intellectual Property Rights Coordination Center, the Federal Trade Commission, the Food and Drug Administration, and the Consumer Products Safety Commission. Our attorneys have also created and/or worked with such industry-wide anti-counterfeiting groups as the International Anti-Counterfeiting Coalition, the International Trademark Association, and other groups. Here are some examples of our anti-counterfeiting and brand protection experience:

- Venable provides comprehensive, global anti-counterfeiting and brand protection programs for a wide range of clients in a variety of industries, including apparel, art, consumer electronics, consumer products, cosmetics, entertainment and media, footwear, luxury goods, mobile devices, nutraceuticals, tobacco, and toys.
- Venable has been selected as the global brand protection counsel for a Fortune 200 multinational consumer products company that specializes in oral and personal care products.
- Venable worked with a major cosmetics company to develop a more comprehensive global brand protection strategy, advised it on the use and implementation of metrics to measure the return on investment and impact of brand protection activities, and enhanced the effectiveness of its online brand protection efforts, as well as government and industry collaboration efforts.
- Venable manages the global anti-counterfeiting strategy for Playboy and its wide variety of licensed products. This representation includes coordination and oversight of all IP enforcement efforts by foreign counsel.
- Venable manages Sony Mobile's global trademark portfolio and online brand protection program, and provides support and strategic advice to the company's internal anti-counterfeiting and brand protection functions.
- Venable serves as the global trademark and brand protection counsel for a major multinational technology company. Venable works with this company to manage its global trademark portfolio, develop and enhance the company brand protection strategy and IP enforcement program, and coordinate brand protection efforts with foreign counsel around the world.

[For more information, please contact any of our Brand and Content Protection professionals.](#)

About Venable

With more than 600 attorneys in offices across the country practicing in all areas of corporate and business law, complex litigation, intellectual property, and regulatory and government affairs, Venable is one of America's top 100 law firms. For over a century, we have built our firm based on a simple and enduring premise: We see the world through the eyes of our clients. We immerse ourselves in our clients' businesses so that we fully understand the context of their legal issues. By being fully aligned with their legal and business objectives, we are able to deliver creative, integrated solutions that add value to our clients. Our firm is also a story of constancy and thoughtful growth. Our clients enjoy an extra measure of confidence knowing that our every decision – from hiring to building out our service areas and expanding our geographic reach – is informed by our desire to better serve their needs.

Our clients rely on Venable's broad capabilities and experience across an array of disciplines and industries. The businesses we represent cover the full spectrum of industries and organization types, both for-profit and nonprofit, and range from entrepreneurs and emerging growth companies to large national and international organizations. Our lawyers bring a wealth of experience to the challenges and opportunities our clients face, and are recognized in the business and legal communities as the leading practitioners in their fields. Our clients also benefit from the broad perspective that our firm brings, as a large number of our attorneys are former prosecutors, regulators, and lawmakers, as well as inside counsel.

Commitment to our clients is matched by our commitment to the communities in which we and our clients operate. Venable attorneys are leaders and volunteers in philanthropic organizations and perform tens of thousands of hours of pro bono work. The Venable Foundation provides needed financial support to organizations that are indispensable to the least fortunate communities and continues a long tradition of unparalleled giving which complements the pro bono legal work and community service of Venable attorneys and staff.

At Venable, we are proud that our clients come to us to solve their most complex legal issues, relying not only upon the knowledge and skills of our attorneys, but also on our unwavering commitment to outstanding service and valuable counsel.

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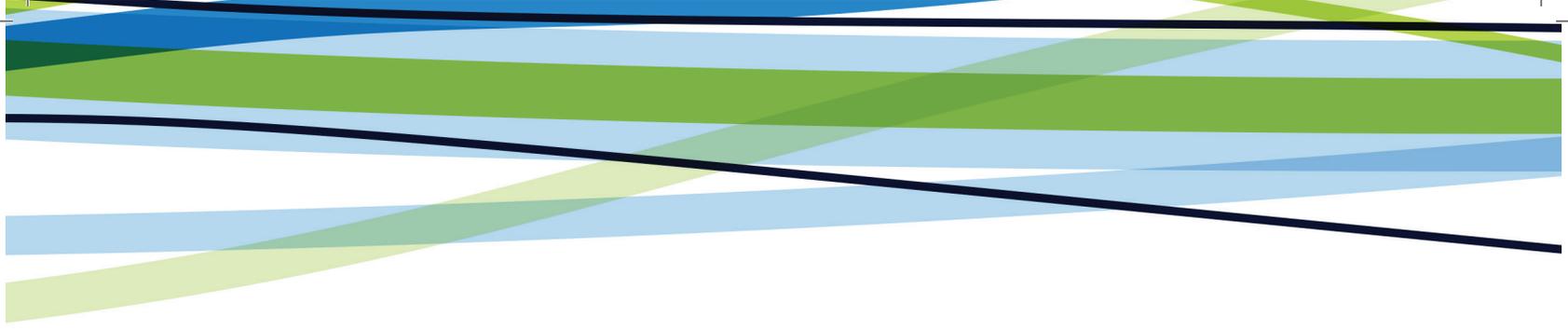
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Meet Us

At SupplySide West

WEDNESDAY, SEPT. 27 – THURSDAY, SEPT. 28

Visit Venable's office space located at the entrance of the Expo Hall for a complimentary, on-site consultation with one of our attorneys to discuss the legal issues facing your business.

WEDNESDAY, SEPT. 27, 3:00 – 4:30 p.m. PT

Join us for a special reception in Venable's space. Meet our team and enjoy complimentary beer, wine, and hors d'oeuvres.

After the show, visit venable.com/advertising/toolkit to download *Venable's Advertising Law Toolkit*, a free set of guides designed to help marketers identify and avoid common advertising pitfalls.

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