



VENABLE_{LLP}

Official Legal and Regulatory Partner
of SupplySide West 2016

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 upon not only the knowledge and skills of our attorneys, but also on our unwavering commitment to delivering 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, 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 Food? 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.

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.

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

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.

State Attorneys General

Venable LLP offers clients a full range of services in its State Attorneys General practice. The firm's work with state attorneys general goes back decades and spans many industries. At any given time, our team is working on more than a dozen active state attorney general matters.

Our State Attorneys General practice has recently been bolstered and is led by former Arkansas Attorney General and U.S. Senator Mark L. Pryor; Erik Jones, who served as Assistant Attorney General and Director of the Policy Bureau for Illinois Attorney General Lisa Madigan; and Kevin L. Turner, who served as Chief Deputy Attorney General for Alabama Attorney General Luther Strange. Senator Pryor, Erik Jones, and Kevin Turner join numerous practitioners who have years of experience crafting creative policy solutions and representing companies of all sizes before state attorney general offices, often in high-profile, multifaceted matters.

In today's policy and legal environment, state attorneys general are more relevant to companies than ever before.

They are involved in state legislative initiatives, multistate investigations, and litigation that affect almost every major U.S. industry. Whether they act alone, in concert with other states, or with the Department of Justice, the Federal Trade Commission, the Consumer Financial Protection Bureau (CFPB), or other federal agencies, their influence is felt in every decision-making body. State attorneys general enforce their states' consumer protection and data breach laws, serve as environmental regulators, and are actively involved in merger review and antitrust regulation. In addition, they are increasingly joining together to advocate before the U.S. Congress on federal policy issues and federal actions.



Venable's State Attorneys General team attends state Attorneys General trade association meetings held by the National Association of Attorneys General (NAAG), the Republican Attorneys General Association (RAGA), the Democratic Attorneys General Association (DAGA), and the Conference of Western Attorneys General (CWAG). These meetings serve as a forum where our attorneys build relationships on behalf of clients and educate state Attorneys General and their teams about our client's industries and their potential (or existing) issues.

Venable offers a variety of practical and strategic solutions in dealing with the attorneys general:

- ▶ We build relationships, educating the state attorneys general and their teams about our clients and our clients' industries.
- ▶ We spend time with our clients to help them develop their approach to the state attorneys general environment and trends. This includes political analysis and advice on a variety of business and litigation topics.
- ▶ We have the substance and experience needed to handle practically any issue presented by a state attorney general working alone or by all of them working together.
- ▶ We work with clients to develop and execute strategies for attorney general inquiries, investigations, and litigation.
- ▶ We identify emerging trends so we can work with clients to anticipate and proactively limit potential problems.
- ▶ We engage on behalf of clients with attorneys general regarding state and federal statutes, regulations, and policies.



Venable has deep experience representing clients before state attorneys general in the following areas:

Advertising and Marketing

For most state attorneys general, false advertising, “bait and switch,” misleading comparisons, and unsubstantiated claims are the traditional concerns of consumer protection. Venable, one of the leading firms in the country in advertising law, consults and litigates in all of these areas.

Antitrust

We regularly represent clients who are facing federal and state challenges relating to anti-competitive activity – whether it is in connection with a merger/acquisition or just in the ordinary course of business.

Consumer Finance

The passage of Dodd-Frank and the creation of the Consumer Financial Protection Bureau have given rise to a new jurisdiction for state attorneys general and numerous new challenges for business. Venable has more experience than our counterparts with the CFPB and the actions they bring.

Consumer Products and Services

The traditional alliance between the Federal Trade Commission and the state attorneys general is as strong as ever. Whether they are working together or on separate tracks, our clients have relied on our services in these areas for decades, with proven results.

Environment and Energy

Environment and energy are emerging areas of focus for the states as more domestic energy is developed and produced, and the EPA and other federal agencies become more active in regulating energy production and consumption.

Investigations

Experience counts. Venable has handled investigations by Congress, federal agencies, and the states for years. In addition to our broad experience, the firm routinely hires attorneys who have run investigations for the federal and state governments. This first-hand knowledge is always a valuable asset to Venable’s clients.

Legislative and Governmental Affairs

With a strong lobbying arm headquartered in its Washington, DC office, our firm is accustomed to getting results. We advocate with Congress, the White House, and virtually all federal agencies, helping clients make their voices heard.

Privacy and Data Security

Privacy and data security is a core strength for Venable, and we have been involved in shaping policy at the federal, state, and local levels. We are skilled at establishing best practices for a company or an entire industry, as well as handling the difficult process of cleaning up after a data breach.

State and Local Government

The Tenth Amendment reserves powers to the states, and most state attorneys general jealously protect this constitutional role. This, coupled with the gridlock in Washington, means we see more state legislative and regulatory activity now than at any time in the past. Venable gives clients the right team to handle situations at the state level.

Trademarks And Brand Protection

protect your brand and online presence

Your brand is your gateway to the world, and trademark law is the primary vehicle for protecting your brand. Venable is a global, award-winning leader in trademark law. We provide a wide range of legal services – from registration to licensing and litigation – to protect and leverage the use of your brand through trademarks, trade dress, social media and domain names. Venable understands that trademark assets are unique, and we know how to address a client's objectives with practical, efficient guidance, designed to accomplish its commercial goals.

Venable's trademark team – bolstered by five former USPTO trademark examiners and two former in-house counsel – has been a leader in trademark filings for many years. In addition to earning national first-tier ranking in U.S. News – Best Lawyers "Best Law Firms," we rank among the leading law firms in terms of applications filed and registrations issued. Since 2012, World Trademark Review 1000 – The World's Leading Trademark Professionals among the top firms in the United States - DC Metro area, has recognized Venable's trademark practice. Several of our partners have also earned individual rankings.

Our trademark practice is world-class, managing 36,000 trademark applications/registrations, including full domestic and international portfolios for leading companies.

Venable's international trademark experience extends to six continents through an established network of foreign counsel. Our practitioners are well versed in filing under the Madrid Protocol and in its benefits and costs. We frequently advise clients regarding the most effective and cost-efficient means of providing trademark protection in foreign markets, including recordation of licensing agreements for better brand enforcement. We also assist in coordinating and managing trademark disputes worldwide, including opposition and cancellation proceedings, and litigation before foreign courts.

Members of our trademark group have been elected to positions in international trademark organizations, such as INTA and Marques, the European Trademark Owners Association. Through these organizations, we have become familiar with other legal systems and have built strong personal and professional relationships with top foreign lawyers around the globe.

*Venable:
A Leader In
Trademarks.
A Law Firm
With Global
Reach.*

Representative Matters:

- › Venable manages the international trademark portfolio of one of the world's leading mobile phone manufacturers, including contentious and non-contentious matters, domain name counseling and dispute resolution, and advertising review and clearance.
- › Venable manages and enforces the global trademark portfolio of a leading global higher-education company.
- › Venable is responsible for global trademark prosecution and enforcement, including anti-counterfeiting, for Playboy. The portfolio covers over 10,000 marks in 190 countries.
- › Venable manages and maintains the full range of trademark work, including portfolio management and copyright work, for a global investment management firm.
- › Venable provides strategic planning for worldwide protection of primary brands to a major American film and television production company.
- › Venable represented Arianna Huffington in negotiating intellectual property aspects of the sale of The Huffington Post to AOL.
- › Venable manages the trademark portfolio of Perdue Farms Inc., the third-largest poultry company in the United States, including contentious and non-contentious disputes, domain name counseling, and advertising review and clearance.
- › Venable helped a fast-casual restaurant successfully register its key brand in the European Community. This ended a seven-year battle to register the name.
- › Venable manages the international trademark portfolio of a European hotel chain.
- › Venable, working with local European counsel, helped win an important appeal for one of the world's leading mobile phone manufacturers in its bid to register a rare motion trademark in the European Community.
- › Venable stopped a sham technology outsourcing company from using our client's well-known Internet hosting brand on Facebook to attract victims to its business and websites.
- › Venable obtained a temporary restraining order, a permanent injunction and \$100,000 damages to shut down an online trademark infringement in which a Ponzi-scheme operator in Iran was impersonating a hedge-fund client.
- › Venable fended off a motion for a temporary restraining order which would have prevented its client from applying for a key new global top-level domain.
- › Venable prevailed after a full trial on the merits and post-trial briefing at the Trademark Trial and Appeal Board to cancel a registration for a tequila trademark on behalf of a client with earlier rights in a similar mark for rum.



International Trade And Customs

inbound, outbound—we help you navigate past your regulatory hurdles

In spite of the strong tide of globalization, the mechanics of doing business across oceans and borders are more challenging than ever. The rewards may be greater, but the hurdles keep growing.

With increased enforcement of trade rules both here and abroad, Venable trade attorneys help clients solve everyday issues—such as classifying products and obtaining export control authorizations. We help clients create business strategies that optimize savings through preferential trade programs and help them reduce their costs of doing business effectively around the globe.

ADVOCACY BEFORE REGULATORY AGENCIES



INBOUND | Import and Customs

- › Customs and Border Protection (CBP)
- › International Trade Commission (ITC)
- › Commerce's Import Association (IA)
- › Committee on Foreign Investment in US (CFIUS)
- › Consumer Products Safety Commission (CPSC)

OUTBOUND | Export Controls

- › Directorate of Defense Trade Controls (DDTC)
- › Bureau of Industry and Security (BIS)
- › Office of Foreign Assets Control (OFAC)
- › Census Bureau's Foreign Trade Division
- › Customs and Border Protection (CBP)

We handle all aspects of international trade. *How this works to your benefit...*

Venable trade attorneys see the big picture, as well as all of the details. Because we're in touch with decision makers on all sides of trade issues, we can alert you to evolving trends in trade policy and enforcement. We advise clients on how to set up procedures that keep goods moving and remove roadblocks to transactions and thereby reduce compliance costs.

We're well known in Washington. *How this works to your benefit...*

We are headquartered near the relevant government agencies—the Departments of State, Commerce and Treasury, the U.S. Customs and Border Protection (CBP) and the many other agencies—where decisions are made that affect your business. More importantly, Venable attorneys include former agency officials and possess, on average, more than 20 years' experience.

Long-standing connections around the world. *Yet another benefit...*

We work closely with a wide network of experienced trade attorneys in countries around the world—attorneys with exactly the right skills to accomplish what you need, wherever you need it.

INBOUND

Import and U.S. Customs issues. We cover the entire range of issues and procedures involved in importing goods into the United States—entry procedures, tariff classification, duty preference programs, country-of-origin marking and labeling, protests, assessment audits and prior disclosures. We obtain product Customs rulings, help clients deal with restrictive quotas, as well as confirm eligibility under preferential trade programs such as the North American Free Trade Agreement (NAFTA), the Generalized System of Preferences (GSP) and numerous bilateral and multilateral agreements.

We also assist clients in gaining the benefits of participating in various CBP programs including the Customs-Trade Partnership Against Terrorism (C-TPAT) and Importer Self-Assessment (ISA) programs.

Focus on avoiding problems with Customs and other government agencies at the border. Importers call on us to represent them in U.S. Customs audits, and in dealing with detentions, forfeitures, seizures and other enforcement and penalty actions. For several Fortune 100 companies, we conduct pre-audit import and export compliance assessments, including developing corporate-wide, multi-location assessments and tailored training programs.

OUTBOUND

U.S. export controls. Clients rely on Venable for our deep understanding of the complex U.S. trade regulations governing exports. We provide advice and guidance on all aspects of exporting items, software, technology and defense services from the United States, as well as on “deemed exports” which occur within the U.S. We are skilled in solving issues associated with export controls and embargoes, including compliance with the regulations administered by the Bureau of Industry and Security, the Directorate of Defense Trade Controls and the Office of Foreign Assets Control.

We evaluate proposed transactions, seek classification rulings, obtain licenses and authorizations, develop compliance programs and conduct compliance audits and training for employees, agents and distributors alike. When problems arise, we represent exporters in investigations and enforcement proceedings. Our experience also includes guiding companies in their compliance with the Foreign Corrupt Practices Act (FCPA), the Foreign Agent Registration Act (FARA) and the anti-boycott laws. In other countries, our well-established relationships with knowledgeable trade counsel provide clients with the skills and experience needed to resolve problems related to maintaining worldwide supply-chains and distribution networks.

TRADE DISPUTES

Resolutions of domestic and international issues. We represent companies involved in all types of trade disputes—often defending clients in antidumping and countervailing duty investigations, safeguard disputes and other matters before the Department of Commerce, International Trade Commission and Office of the U.S. Trade Representative. Venable trade attorneys also handle litigation and appeals arising from such proceedings. We regularly practice before the U.S. Court of International Trade and Court of Appeals for the Federal Circuit. We protect your interests overseas as well, representing clients in global trade disputes including those before the World Trade Organization.

TRADE STRATEGIES

Positioning you to achieve your goals. We advise clients in developing and executing strategies that enable them to expand their businesses. This often involves many moving parts—strategic sourcing, sales and distribution arrangements both in the U.S. and abroad, compliance with export controls, use of foreign agents, affiliated offices and joint ventures. When needed, we collaborate with Venable’s Legislative advisors to promote trade policy initiatives and decisions of the Executive Branch or to affect legislative matters in the U.S. Congress, which can impact a client’s interests.

Our understanding of the regulatory, legislative and commercial issues affecting international trade can translate into practical solutions for your business. Moreover, our familiarity with the relevant agencies assures that you are alerted to coming changes in time to adjust your strategies and take advantage of new factors in international trade.

Meet Our Team



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