ACI American Conference Institute

In Collaboration with the Council for Responsible Nutrition — The Science Behind the Supplements

Now Virtual

8th Annual Legal, Regulatory and Compliance Forum on

# DIETARY SUPPLEMENTS

*A comprehensive guide to the latest developments affecting "products intended to supplement the diet"*

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**VIRTUAL CONFERENCE & WORKSHOPS**
**June 23–24, 2020**
**June 25, 2020: Workshops on CBD and International Commercialization**

## Distinguished Co-Chairs:

**Scott Bass**
*Partner & Head, Global Life Sciences*
**Sidley Austin LLP**

**Steve Mister**
*President & CEO*
**Council for Responsible Nutrition**

## Fireside Chats with:

**Steven Tave**
*Director, Office of Dietary Supplement Programs*
**U.S. Food and Drug Administration**

**Serena Viswanathan**
*Acting Deputy Director, Bureau of Consumer Protection*
**U.S. Federal Trade Commission**

## Insights from Key Government Agencies and Consumer Protection Groups:

U.S. Food and Drug Administration
U.S. Federal Trade Commission
California Chamber of Commerce
National Advertising Division (NAD)® – BBB National Programs, Inc.

## Perspectives from Leading Industry Stakeholders:

Abbott
Atrium Innovations
Charlotte's Web
Chromadex
CV Sciences, Inc.
dōTERRA
Herbalife Nutrition
Nature's Bounty
Neptune Wellness Solutions
Nutraceutical Corporation
OmniActive Health Technologies Inc
Papa & Barkley LLC
Pharmavite
RB Health US, LLC

## 2020 Program Highlights

- Focus Session on Addressing **Inconsistent Interpretations of the Dietary Supplement Definition**
- Case Study on the Best Way of Establishing Ingredient Safety: **NDI notification vs. GRAS determination**
- Spotlight on The Current Status of a **Legal Path for CBD in Dietary Supplements**
- Think Tank on **Increased State Consumer Protection Activity**
- Risk Assessment of **Innovative Claims** and the Use of **Influencers** in Product Promotion
- Forecast on New FDA Guidance on **Certificates of Free Sale**
- Trend Analysis for **Postbiotics, Prebiotics and Probiotics**
- Best Practices Implementation for **Meeting Different Retailer-Imposed Quality Requirements**
- **Supply Chain Integrity, Transparency**, and **Corporate Social Responsibility** Assessment

# American Conference Institute (ACI) together with the Council for Responsible Nutrition (CRN) invite you to join us at the Industry's Premier Legal and Regulatory Dietary Supplements Conference...now in a Virtual Format.

*Dear Colleagues:*

We're going virtual! When we began planning this year's conference, I intended to reflect on the relatively crisis-free, productive year the industry had enjoyed in 2019—sales up modestly, few regulatory actions, strong consumer interest—little did I know what 2020 and COVID-19 would bring. The dietary supplement industry has been relatively unscathed from the damaging, confidence-robbing media stories we've seen in previous years. That's due in large part to many efforts across the industry to strengthen quality, reassure consumers, and demonstrate the scientific backing for our products. The industry has used this goodwill and momentum productively to advance important regulatory initiatives and build consumer confidence.

And that's been rewarded by the dramatic increase in sales during the unfolding COVID-19 crisis. Still unclear is how consumers will respond in the face of a tough global economy and new challenges for healthcare. Industry must remain vigilant to address the challenges from this unprecedented crisis, ensure consumers still have access to safe and quality products, and not lose sight of the important initiatives that will set the industry up for success for years to come.

Other issues are also top of mind, like CBD. While FDA has issued warning letters and public statements, but there's a growing sense that the agency is complicit in creating a rogue market by its inaction. What is the pathway forward for legal supplements containing CBD? That leads to even greater questions concerning approval of new ingredients generally and issuance of the final NDI guidance. Many argue that it is time for DSHEA 2.0, but questions persist regarding aspects of DSHEA 1.0—such as the very definition of a dietary supplement. Topics like mandatory product listing, eliminating what some call the "GRAS loophole," and FDA authorization of third-party inspectors for GMPs are ideas gaining traction.

And let's not forget private class actions and state AGs as sources of concern for supplement marketers. Class action attorneys have found this industry and companies need to be both litigation resistant and litigation ready. We must not only react to legal threats and efforts to undermine the public's trust in our products, but also focus on our innovation, self-policing initiatives, and scientific proof that our products really do benefit the public.

This year's conference will focus on the new era we are entering – ensuring continued compliance, while learning how to address the new challenges. We will examine immune function claims in the era of COVID-19 and supply chain disruptions caused by the global pandemic. We'll also explore NDI notifications vs. GRAS submissions, the impacts of state consumer protection activity, the latest on Prop 65 and class action litigation, new developments in probiotics, prebiotics, and now postbiotics, as well as the increasing international trade issues that have implications for everyone—like tariffs, Brexit, and trade barriers at Codex.

ACI and CRN have collaborated to produce an agenda ripe with topics reflecting today's most pressing industry concerns. We have included interactive sessions to help explore resolutions to complex new challenges and ongoing obstacles. Be part of this industry-leading event, network with your peers and join us to learn what's new—as well as have some fun.

We look forward to seeing you virtually this June.

Steve M. Mister

**Steve Mister**
*President & CEO*
**Council for Responsible Nutrition**

# Distinguished Faculty

## CO-CHAIRS

**Scott Bass**
*Partner & Head, Global Life Sciences*
**Sidley Austin LLP (New York, NY)**

**Steve Mister**
*President & CEO*
**Council for Responsible Nutrition (Washington, DC)**

## SPEAKERS

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*Member*
**Cozen O'Connor (Washington, DC)**

**Christine Beltran**
*Director, Global Product Regulatory Services*
**dōTERRA (Pleasant Grove, UT)**

**Paul Bolar**
*VP, Regulatory Affairs*
**Pharmavite LLC (West Hills, CA)**

**Jennifer Boyd**
*Director, Regulatory Affairs US & International*
**Atrium Innovations (Sudbury, MA)**

**Ryan Bradley, ND, MPH**
*Director of Research, Helfgott Research Institute*
*Program Director, Building Research across Inter-Disciplinary Gaps (BRIDG) Clinical Research Training Program*
*Associate Professor, College of Naturopathic Medicine and School of Graduate Studies*
**National University of Natural Medicine**

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**Pharmavite LLC (West Hills, CA)**

**Ricardo Carvajal**
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**Hyman, Phelps & McNamara, P.C (Washington, DC)**

**Richard Cleland**
*Assistant Director; Advertising Practices, Bureau of Consumer Protection*
**U.S. Federal Trade Commission (Washington, DC)**

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**Neptune Wellness Solutions (Los Angeles, CA)**

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**Julie L. Hussey**
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**Perkins Coie LLP (San Diego, CA)**

**Sameer Joshi**
*Head of Global Business Operations*
**OmniActive Health Technologies (Morristown, NJ)**

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**Herbalife International of America, Inc. (Los Angeles, CA)**

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**Herbalife Nutrition (Torrance, CA)**

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**Venable LLP (Washington, DC)**

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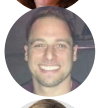
*Senior Vice President Scientific & Regulatory Affairs*
**CV Sciences, Inc. (San Diego, CA)**

**Christine McInerney**
*Deputy General Counsel – Litigation*
**Nature's Bounty (Ronkonkoma, NY)**



**Russ Michelson**
*Regulatory Director, VMS, RB Health*
**RB Health US, LLC (Parsippany, NJ)**

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*Vice President and Associate General Counsel*
**Council for Responsible Nutrition (Washington, DC)**

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*Partner*
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**California Chamber of Commerce (Sacramento, CA)**

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**Chromadex (Los Angeles, CA)**

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*Senior Vice President of Government Affairs & Corporate Communications*
**Charlotte's Web (Boulder, CO)**

**James McCall Smith**
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**Stan Soper**
*Outside General Counsel*
**Nutraceutical Corporation (Park City, UT)**

**Ashish R. Talati**
*Partner*
**Amin Talati & Wasserman LLP (Chicago, IL)**

**Steven Tave**
*Director, Office of Dietary Supplement Programs*
**U.S. Food and Drug Administration (Washington, DC)**

**David Trosin**
*Managing Director – NSF Health Sciences Certification*
**NSF International (Ann Arbor, MI)**

**Jessica Wasserman**
*Partner*
**Greenspoon Marder LLP (Washington, DC)**

**Chad Weida**
*Associate Director, AN Regulatory Affairs US, Canada, Puerto Rico*
**Abbott (Columbus, OH)**

**Serena Viswanathan**
*Acting Deputy Director of the Bureau of Consumer Protection*
**U.S. Federal Trade Commission (Washington, DC)**

**Complete your conference experience and additional networking opportunities by attending the post-conference workshops* on June 25th:**

**A Working Group on**
Compliant Commercialization of Hemp-Derived CBD Dietary Supplements

**B Working Group on**
International Dietary Supplement Commercialization in the Current Geopolitical Climate

** Your conference registration includes both workshops.*

*See page 9 for details.*

# Conference Day One Tuesday, June 23, 2020*

**All timings are Eastern Daylight Time.*

8:30 Virtual Conference Login

8:45

## Co-Chairs' Welcoming Remarks

**Scott Bass**
*Partner & Head, Global Life Sciences*
**Sidley Austin LLP**

**Steve Mister**
*President & CEO*
**Council for Responsible Nutrition**

9:00

## State of the Industry Address: The New Normal for Supplements

Over the last few years, the dietary supplement industry has invested considerable energy and resources to promote consumer confidence in its products. At the same time, companies are facing increased legal threats from consumer class actions – which are not only costly for the industry, but stand to undermine public trust. Innovation, increased transparency, and attention to science have been key factors in building confidence and should also be harnessed to combat these legal threats.

New products, innovative modes of product delivery, development of robust industry audit standards, and a voluntary registry program coupled with a greater number of scientific studies that support the benefits of these products are indicative of the industry's new era of responsibility, as well as responsiveness. These measures, against the backdrop of robust discussions on potential DSHEA amendments, are inspiring industry stakeholders to envision a bright future for dietary supplements.

At the same time, the unexpected and unprecedented COVID-19 pandemic is wreaking havoc on supply chains, threatening worker safety, and challenging companies to continue to provide safe, quality, and beneficial health products in ways that have never been seen before. Now more than ever supplement companies have a responsibility to ensure compliance across all parts of the manufacturing process and continue to provide products that support consumer health during these challenging times.

This opening session will provide attendees with a view on the state of the dietary supplement market, a forecast for the future, and the industry's continued commitment to promote good health with good products.

9:25 Break

9:30

## FDA Fireside Chat

**Steven Tave**
*Director, Office of Dietary Supplement Programs*
**U.S. Food and Drug Administration**

INTERVIEWED BY:

**Steve Mister**
*President & CEO*
**Council for Responsible Nutrition**

10:00 Morning Break

10:20

## Defining a "Dietary Supplement" as Intended by DSHEA: Examining Questions Surrounding Synthetic Botanical Constituents, Drug Exclusions, and Other Inconsistent Interpretations of the Dietary Supplement Definition

The introduction of novel ingredients and new technologies over the years have tested how a "dietary supplement" is defined under DSHEA — thus, presenting companies with a variety of complex challenges as to what truly can be classified as a supplement. Industry has spent a lot of time debating how these issues could be fixed with changes to DSHEA, but what's a company to do now? This panel will explore how a company can navigate these challenges while living in a DSHEA 1.0 world.

Topics of discussion include:

- Determining whether the definition of a dietary supplement leaves room for synthetic copies of botanical ingredients?
  - » Understanding the FDA's position on synthetic botanical constituents
- Comprehending how the drug exclusion provision of DSHEA impacts dietary supplements
  - » Comparing drug exclusions for food vs. drug exclusions for dietary supplements
  - » Assessing how the drug exclusion provisions impact FDA enforcement actions
  - » Analyzing how the drug exclusion provisions affect innovation for new dietary ingredients
- Surveying how the clause "dietary substance for use by man to supplement the diet by increasing the total dietary intake" has been interpreted by FDA

11:15 Break

11:20 CASE STUDIES

## NDI Notifications vs. GRAS Determinations: are Exceptions Swallowing the Rule?

As talks of improving DSHEA continue, stakeholders seek clarity on how to comply with new ingredient safety requirements in an efficient and commercially viable manner. Companies struggle with questions about FDA engagement in the NDI notification process, whether an ingredient's safety needs to be established through an NDI notification or whether it can be considered GRAS, and how to protect confidential, proprietary data throughout the process.

In this session, our speakers will discuss the process for NDI notifications vs. GRAS determinations, all the while providing concrete real-word examples of outcomes, success stories, and lessons learned.

Topics of discussion will include:

## NDI

- Pinpointing challenges with submitting an NDI notification without a final NDI guidance from FDA
- Outlining the steps needed to notify FDA of an NDI, data necessary to demonstrate that an ingredient will reasonably be expected to be safe, and commercial considerations companies should be aware of during this process
  - » Tools to help protect confidential data from public disclosure
  - » Tips to engage with FDA and solicit meaningful feedback from the agency to help ensure a successful NDI filing
- Assessing the reasons why a company might not submit an NDI notification
  - » Examining manufacturers' hesitancy to share proprietary information
  - » Assessing consequences of other companies "piggybacking" on initial NDI filers data
- Creating master files and evaluating IP protections for NDI notifications
  - » Lessons learned from the pharmaceutical industry that can be applied to the dietary supplement process
  - » Considerations for FDA to incentivize development, notifications, and protect responsible companies

## GRAS

- Examining ways dietary supplement manufacturers use GRAS determinations to legally market a dietary supplement
- Determining when a GRAS determination vs. NDI notification is appropriate
- Understanding the practical differences between GRAS determinations vs. NDI notifications

12:20 Lunch Break

1:20 **CASE STUDIES**

## CBD-Hemp State of the Union: Threats Caused by Government Inaction and the Current State of a Legal Path for CBD in Dietary Supplements

- Clarifying the latest information on FDA's position on CBD use in dietary supplements and food
- Anticipating whether FDA will consider an approval pathway for CBD in supplements and food, and possible restrictions on that pathway
- Understanding the significance of FDA warning letters issued to companies that sell CBD products as dietary supplements
- Comprehending how government inaction has significantly increased class action threats for CBD and could threaten the viability of the industry moving forward
- Analyzing Congressional positions and recent legislation to exempt CBD from the drug exclusion provisions currently preventing CBD use in supplements and food
- Examining state regulation and legislation for CBD and how these actions could impact the federal regulatory landscape, *e.g.*, California's pending assembly bill AB228 allowing the sale of hemp-derived CBD in food – could this put additional pressure on FDA?
- Exploring steps industry can take to mitigate risk and put pressure on legislators and regulators to clear a legal pathway for CBD

2:20 Break

2:25

## The Impact of Increased State Consumer Protection Activity on the Dietary Supplement Industry: Analysis of Pending and Recent State Initiatives and How They Could Affect Your Company

- Analyzing the potential impact of regulatory initiatives that could increase class action risks
  - » How industry can combat these, such as the risk posed by recent regulatory changes proposed in Oregon
- Understanding how sale limitations that state legislators have proposed for dietary supplements, such as age and ingredient restrictions, would make it harder to distribute dietary supplements and create a slippery slope of patchwork state regulations
- Examining ways in which state privacy laws, such as *California's Consumer Privacy Act (CCPA)*, are uniquely affecting dietary supplement companies
  - » Comprehending the impact of privacy laws and legislation on the dietary supplement industry's efforts to innovate through e-commerce and digital marketing
  - » Assessing unique considerations for dietary supplement companies, such as how consumers' "right to be forgotten" may affect future safety concerns (*e.g.*, what if a consumer needs to be notified of a recall)
- Exploring how broad state environmental legislation and consumer concerns could change how supplements are sold

3:25 Afternoon Break

> *"Comprehensive and in-depth review of leading regulatory issues for the dietary supplement industry."*
>
> **Chad Lewis, Chief Operating Officer, Universal Nutrition**

3:45

## Examining New Trends in Claims Substantiation: A Study of Innovative Claims, the Ever-Increasing Use of Influencers, and Risk

### Innovative Claims

- Exploring the latest trends in claims and developing substantiation for these claims
- Assessing claims related to packaging and waste reduction
- Evaluating newer claims related to probiotic and prebiotic products
- Reviewing various types of environmental ("green") claims and substantiation challenges surrounding their use
- Understanding the benefits and pitfalls of making complicated structure/function claims
- Reviewing recent FTC activity concerning performance, efficacy, and comparative claims
- Comprehending what the FTC's increased scrutiny over sales claims made by direct-selling companies could mean for your business

### Influencer Marketing

- Exploring the concept of organic influencers and related risk unique to dietary supplement companies, such as ensuring that influencers not only make statements that can be supported, but do not make disease claims or other inappropriate statements
- Devising strategies for monitoring content across different social media platforms
- Drafting legal contracts and developing training to ensure influencers understand what is required of them and know the consequences for violating these requirements
- Examining the FTC's latest guidance on influencer marketing
- Analyzing legal compliance challenges unique to using influencers to promote FDA-regulated products

### Special Focus on: Immune Function Claims – Viewpoints on Substantiated v. Fraudulent in a COVID-19 Environment

- Hear from an immunity expert about the science behind immune support claims and how certain dietary ingredients benefit our immune system
- Learn from advertising law experts how to talk about dietary supplement health benefits in a COVID-19 world
- Understand the FDA's and FTC's latest actions against COVID-19 claims

5:15 Break

5:20

## Anticipating Post-Implementation Challenges with the BE Label

Full implementation of USDA's bioengineered (BE) food label requirements went live on January 1, 2020. This panel will explore post-implementation challenges and address anticipated enforcement activity and other risks.

Points of discussion will include:

- Identifying potential post-deadline challenges relative to proper disclosure of bioengineered foods
- Understanding exceptions to the BE labeling rule
- Assessing the USDA's position on the use of technology for BE disclosures
- Ensuring proper labeling for known BE Foods
- Anticipating whether consumer litigation will follow that alleges non-compliance with labeling requirements
- Analyzing continued state interest in BE labeling requirements

5:50 Conference Adjourns to Day Two

## Continuing Legal Education Credits

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# Conference Day Two Wednesday, June 24, 2020*

**All timings are Eastern Daylight Time.*

8:00 Virtual Conference Login

8:30

## Conference Co-Chairs' Welcome Remarks and Recap of Day One

8:45

## Fireside Chat: FTC Priorities and Enforcement Initiatives

**Serena Viswanathan**
*Acting Deputy Director of the Bureau of Consumer Protection*
**U.S. Federal Trade Commission**

INTERVIEWED BY:

**Megan Olsen**
*Vice President and Associate General Counsel*
**Council for Responsible Nutrition**

9:15 Break

9:20

## International Affairs: Supply Chain Disruptions and Contract Negotiations in the Times of Tariffs and COVID-19

- Understanding COVID-19 impacts on supply chain and how to combat them
  - » Exploring contractual rights and how to draft contracts in an uncertain world
  - » Examining supply chain risks from COVID-19, such as increased risk of economic adulteration and how to source new suppliers quickly and efficiently
- Examining the status of tariffs and treaties currently impacting the dietary supplement industry
- Exploring the impact of tariffs on raw material and ingredient imports from and exports to relevant countries such as China
- Understanding the possible impact of the new USMCA on the dietary supplement industry
- Assessing the possible Brexit effect on the dietary supplement industry
- Analyzing the long-term effects of tariffs and related costs on the consumer
- Examining the impact of pending legislative initiatives to restore congressional authority over tariffs and taxes

10:05 Morning Break


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10:25

## Prebiotics, Probiotics, and Now Postbiotics: Addressing Current Standards and International Guidelines

- Analyzing new trends associated with prebiotic products in dietary supplements
- Assessing the current debate on probiotic standards and international guidelines
  - » Examining current Codex standards for dietary supplements as they apply to probiotics
  - » Considering proposed Codex standards specific to probiotics offered by the International Probiotics Association (IPA) and opposition from the International Alliance of Dietary/Food Supplement Associations (IADSDA)
- Understanding FDA's labeling requirements and industry best practices for probiotics, such as quantity and identity labeling challenges
- Examining the impact of the lactobacillus taxonomy name change
- Exploring the rise of postbiotics and its impact on dietary supplement products
- Revisiting the *Bayer* case – implications five years later for probiotics and beyond

11:05 Break

11:15 CASE STUDIES

## Focus on Quality Standards: Implementing Winning Strategies for Meeting Retailer and Consumer Demands for Quality

- Ensuring compliance with the ANSI/NSF 455-2 good manufacturing compliance (cGMP) certification standards developed by the Global Retailer and Manufacturer Alliance (GRMA)
- Understanding the significance of the Supplement Safety and Compliance Initiative (SSCI) benchmarking guidance documents
- Developing best practices for meeting different retailer-imposed quality requirements and managing retailer expectations
  - » Exploring CVS's "Tested to be Trusted" program for dietary supplements for label accuracy and safety over one year after implementation
  - » Tips for how to manage differing retailer requirements and streamlining quality-compliance programs
- Understanding the impact of testing done through an independent third-party lab
- Outlining the impact of self-regulatory standards led by industry and consumer stakeholders
  - » Building consumer confidence and ensuring safety of dietary supplement ingredients

12:00 Lunch Break

1:00

## Ensuring Supply Chain Integrity and Transparency, and Meeting Corporate Social Responsibility Expectations

In this panel, our speakers explore the processes and methods for ensuring supply chain integrity, social and environmental responsibility, as well as improving transparency and managing counterfeit threats.

Topics of discussion will include:

- Understanding how consumer demand is influencing dietary supplement manufacturers to be more transparent about the source of ingredients
  - » Determining country of origin, labeling requirements, and how to support claims
  - » Resolving challenges with adulterated products caused by supply chain problems
- Managing your own and retailer corporate social responsibility expectations
  - » Environmental; adhering to labor laws; other ethical practices
- Protecting brand image and integrity by monitoring counterfeit products sold on third-party websites
  - » How to detect counterfeits
  - » Establishing crisis management protocols
- Improving GMP standards to maintain supply chain integrity and ensure the continued quality and safety of dietary supplement ingredients
- Assessing FDA supply chain activity related to supplement manufacturers
  - » Debating whether a mandatory product registry will resolve transparency challenges
- Lessons learned from a recent recall related to adulterated dietary supplements

1:45 Afternoon Break

2:05 **HYPOTHETICALS**

## Understanding How Ingredients are Placed on the Prop 65 Lists

Dietary supplement sales practices are significantly impacted by requirements imposed on substances subject to California's Lists of Known Carcinogens and Reproductive Toxicants, better known as Prop 65. Through the use of hypotheticals, this interactive session will explore the various methods by which a substance gets placed on the Prop 65 lists, what can be done to prevent (or at least reduce the chance of) listing, and if a substance is listed, how to reduce its impact.

Attendees will also benefit from an analysis of new Prop 65 developments.

Topics of discussion include:

- Exploring how an ingredient receives a Prop 65 designation
  - » Mechanisms and processes
- Understanding the safe harbor provisions and related requirements
- Determining whether once a product is assigned a Prop 65 designation if it can be removed from the list
- Creating internal processes and protocols to ensure you are meeting Prop 65 requirements
- Examining how new substances recently added to the list may affect supplement manufacturers, such as new listings for soluble nickel and THC
- Assessing new warnings related to acrylamide

2:50 Break

2:55

## Responding to Thorny Class Action Litigation Claims

- Comprehending the significance and class action implications of *Debernardis v. IQ Formulations, LLC*, No. 18-11778 (11th Cir. 2019)
  - » If FDA declares that a product is illegal, is its value negated, thereby giving a right to sue based on economic harm?
  - » How can companies limit application of this case when selling products that are subject to unsettled FDA positions on legality
- Analyzing new class litigation concerning CBD products
  - » Understanding the significance on the recently imposed stay in the *Green Roads of Florida* LLC case
  - » Invoking the doctrine of primary jurisdiction in the absence of FDA guidance on CBD
  - » California CBD class action activity: understanding the parallels between *California's Sherman Act*, the federal *FD&C Act*, and how they relate to these lawsuits
- Analyzing recent trends for the type of claims targeted by class action litigation

3:45 Conference Ends

> *"Awesome opportunity to learn first hand knowledge from those with expertise in the field of Dietary Supplements."*
>
> **Saquib Javaid, Director of R&D/Quality, NutraBlend Foods**

# Post-Conference Workshops Thursday, June 25, 2020*

9 am – 12:30 pm **All timings are Eastern Daylight Time.*

## A WORKING GROUP ON

## Compliant Commercialization of Hemp-Derived CBD Dietary Supplements: Understanding the Current Domestic and International Legal Status and How to Manage Legal Risks for Distributing Hemp-Derived CBD Products

As consumer demand for supplements containing hemp-derived CBD grows stronger, dietary supplement manufacturers need to be aware of applicable laws and regulations, as well as risks associated with successful product launches and viable and compliant commercialization. Legitimate supplement makers seeking to launch CBD products must continue to play by the dietary supplement rulebook, as they always have, and develop appropriate systems to ensure product safety and quality, in the absence of clear FDA guidance and a legal path for CBD in supplements. This workshop will provide an A to Z guide for getting your product on market and avoiding scrutiny through playing by the rules.

Topics of discussion include:

### Legal, Regulatory and the Industry Standards

- Understanding current FDA position regarding the use of CBD in dietary supplements and foods
  - » Lessons learned from recent FDA warning letters
- Examining the DEA's perspective on hemp and its removal from the Controlled Substances Act
- Understating the effect of the 2018 Farm Bill nearly two years after its passage
- Comparing and contrasting federal and state laws on CBD use
- Assessing how industry best practices for other botanical and similar ingredients may help CBD companies develop safe and effective products
- Recognizing gaps where current standards do not address challenges with manufacturing CBD
- Understanding what industry stakeholders can glean from the FDA's approval of the drug Epidolex

### Developing Strategies for Successful Market Entry

- Understanding the steps needed to place your product on the market from start to finish
- Examining current consumer perceptions about CBD
- Outlining the risks and liabilities associated with using CBD in dietary supplements
- Devising effective strategies for developing claims substantiation and labeling that helps reduce legal risks
- Avoiding disease claim and other prohibited claims

### International Perspectives

- Surveying international rules and regulation for hemp-derived CBD
  - » Comparing and contrasting the various rules and regulations of hemp-derived CBD in dietary supplements in Europe vs. Asia vs. Latin America
- Examining the European Food Safety Authority (EFSA)'s position on CBD

12:30 pm – 1:30 pm Lunch Break

1:30 pm – 5:00 pm

## B WORKING GROUP ON

## International Dietary Supplement Commercialization in the Current Geopolitical Climate

In this session, our speakers will help you devise strategies to ensure cross-border commercial success, while still complying with complex rules and regulations specific to individual countries.

Topics of discussion will include:

- Devising strategies for successful market entry into foreign countries
- Examining current trade agreements, U.S. foreign policy, and tariffs impacting dietary supplements
- Assessing tariffs imposed on imported and exported dietary supplement ingredients and raw materials
- Examining various registration requirements and roles of different agencies within foreign countries
- Understanding current updates to international laws and regulations
  - » Assessing Ireland's efforts to enact a tax on food supplements
  - » Exploring the impact of Brazil's changes in the regulation of dietary supplements
  - » Understanding the impact of new regulatory initiatives from China's State Administration of Market Regulation
  - » Realizing the effects of the updated registration process for entry into the Australian and South African markets
- Assessing the effect of the COVID-19 crisis on supply chains
- Addressing international controversies over probiotics labeling and standards
  - » Labeling challenges
  - » Lack of harmonization of laws within the EU

# Annual attendance is comprised of key industry stakeholders from the following functions:


*"As a member of a dietary supplement regulatory affairs department reviewing product content daily for FTC/FDA compliance, it was a valuable experience to be in a room with top minds from around the country who could answer my questions."*

**Christine Bardsley, Regulatory Associate, FoodState**

*"The content covered was exceptional with great presentations. Overall, one of the most informative conferences I have attended in a long time."*

**Alicia Wolf, Regulatory Director, RITUAL**

## Who Should Attend:

### Dietary Supplement Industry Representatives:

- In-House Counsel, including generalists and those having responsibility for FDA and FTC compliance and regulatory affairs as well as:
  - Advertising and Promotion
  - IP, Patents and Trademarks
  - Licensing and Business Development
- Officers, Directors and Executives for Regulatory Affairs and Business Development

### Law Firm Attorneys for the Dietary Supplement Industry whose practices focus on:

- FDA and FTC law
- Advertising and Promotion
- Trademarks, Patents and IP

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|---|---|---|
| Conference + Both Workshops | $2,095 | $2,295 |

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