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June 25 – 26, 2024 • New York City Bar Association New York, NY

12th Annual Legal, Regulatory and Compliance Forum on

DIETARY SUPPLEMENTS

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

Spotlight Interviews with:

Christine DeLorme
Attorney, Division of Advertising Practices
Federal Trade Commission

Cara Welch, Ph.D.
Director, Office of Dietary Supplement Programs Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Distinguished Co-Chairs:

Megan Olsen
Senior Vice President & General Counsel
Council for Responsible Nutrition

Taneesha Routier
Director of Regulatory Affairs
Xymogen

Insights from Leading Industry Stakeholders:

- Pharmavite
- Nestlé Health Science
- Reckitt Benckiser
- Metagenics
- Plexus Worldwide
- OLLY PBC
- ChromaDex
- Unilever
- Growve
- NAD
- Abbott
- NSF International

2024 Program Highlights:

- Think Tank on Preparing for the **FDA Reorganization** and **Upcoming Inspection Process Changes**
- Critical Updates on **State Age Restriction Laws and Ingredient Bans** Impacting Supplements
- Industry Collaborative on **Addressing and Combatting Bad Actors** in the Supplements Market
- FDA Activity Round-Up: Forecasts for the Future of **NDIs, Healthy Claims and IND Requirements**
- Focus on the Latest Compliance and Litigation Risks Stemming from **Ingredient Overages**
- Strategy Session on Insulating Yourself from the Latest **Dietary Supplement Class Action Activity**
- Dietary Supplement Advertising Essentials: **Green Claims, Health Claims, Endorsements & Consumer Reviews**

Exhibitor Sponsor: Arnold & Porter

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Informing and Educating the Natural Products Industry

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Business Information in a Global Context

ACI and **CRN** are excited to welcome you back to New York City this Spring for our **12th Legal, Regulatory & Compliance Forum on Dietary Supplements**.

Join us at this year's conference to obtain critical updates on the latest legal, regulatory, and policy developments that will impact industry practices for the remainder of 2024 and beyond.

The FDA Reorganization will soon be upon us, and industry is bracing itself for the full scope of the implications.

The FDA's unified Human Foods Program and new Office of Regulatory Affairs are expected to become a reality in 2024. The supplement industry is still uncertain about how this will alter FDA activity regarding its products. FDA has signaled that inspection process changes will take place. Join us at this year's event to hear from FDA about what the Reorganization will entail, and how FDA field operations dedicated to supplements will soon change.

The states are increasing their focus in supplement safety through new legislation, leaving many wondering what this will mean for interstate compliance and the future of FDA authority.

The states continue to ramp up their activity in the supplements space, with new state ingredient bans, sustainable packaging laws, and growing state age restriction laws and legislation. Attend and benefit from critical updates on the latest state activity, considerations for interstate compliance, and what this trend might mean for the future of FDA authority in this space.

Emerging contaminants continue to pose threats to the supplements industry, and looking to international markets may signal where the next ingredient targets lie.

With titanium dioxide (TiO2) and PFAS continuing to pose threats for the supplements industry, it is critical to comprehend where your compliance and litigation risks lie. Our esteemed faculty will provide insights on this, as well as what the next ingredient targets might be for legislators, enforcers and the plaintiffs' bar.

New FTC guidance will create critical implications for the future of dietary supplement advertising and marketing.

As industry continues to grapple with the implications of FTC's new Health Products Compliance Guidance, the Commission has also just released its finalized new Endorsement Guides as well as a proposed Rule on the Use of Consumer Reviews and Testimonials. It is critical that dietary supplement companies adhere to these latest regulatory guidelines when making claims about their products in advertising.

Learn about this and more at this year's conference

Do not miss the chance to join leading industry stakeholders and explore how the changing legal and regulatory landscape will impact industry policies and practices for the remainder of 2024 and beyond.

We look forward to seeing you in New York this June!

Distinguished Speakers

CO-CHAIRS

Megan Olsen
Senior Vice President & General Counsel
Council for Responsible Nutrition (CRN)

Taneesha Routier
Director of Regulatory Affairs
Xymogen

ESTEEMED SPEAKERS

Rend Al-Mondhiry
Partner
Amin Wasserman Gurnani, LLP

Katie Bond
Partner
Keller & Heckman LLP

Christine Burdick-Bell
Vice President & General Counsel
Pharmavite LLC

Paola Clavijo
Regulatory Associate Director – Policy, Advocacy and Risk Management
Unilever

Veronica Colas
Counsel
Hogan Lovells

Geoffrey Castello
Partner
Kelley Drye & Warren LLP

Tara Lin Couch, Ph.D.
Owner
TLC Regulatory and Laboratory Consulting

Christine DeLorme
Attorney, Division of Advertising Practices
Federal Trade Commission

Kat Dunnigan
Attorney
Davis Wright Tremaine LLP

Jennifer Fried
Partner, Advertising Practice Lead
Finnegan, Henderson, Farabow, Garrett & Dunner, LLP

Miriam Guggenheim
Partner
Covington & Burling LLP

Susan Hewlings
Vice President of Research Affairs
Radicle Science

Anastasia Jones
Regulatory Affairs Director
OLLY PBC

Aliza Karetnick
Partner
Morgan Lewis & Bockius LLP

Candice Kersh
Partner – Advertising, Marketing, and Public Relations Group
Frankfurt Kurnit Klein & Selz

Patricia Kim
Senior Regulatory Counsel
Growve

Mohamed Koroma
Director, R&D
Pharmavite

Lori Leskin
Partner, Co-Chair, Consumer Products Practice Group
Arnold & Porter

Claudia Lewis
Partner
Venable

Seth Mailhot
Partner
Husch Blackwell

David Mallen
Partner, Co-Chair, Advertising Disputes
Loeb & Loeb LLP

Sharon Lindan Mayl
FDA Partner
DLA Piper

Diane McEnroe
Partner
Sidley Austin LLP

Cynthia Meyer
Partner
Kleinfeld, Kaplan & Becker, LLP

Steve Mister
President & CEO
Council for Responsible Nutrition (CRN)

Laura Najera
Head of Regulatory, Americas
Metagenics

Haiuyen Nguyen
Vice President, Regulatory & Nutrition Policy
Council for Responsible Nutrition

Chris Reid
Chief Legal Officer
Plexus Worldwide

Brandi Reinbold
Senior Manager, Technical, Global Health Sciences Certification
NSF International

Jena Rostorfer, MS, RD
Director, US/Canada Regulatory Affairs
Abbott

Patrick Runkle
Senior Litigation Counsel Consumer Protection Branch
U.S. Department of Justice

Barbara Sanchez
General Counsel
Nestlé Health Science U.S.

Allyn Shultis
Executive Director
Global Retailer and Manufacturer Alliance (GRMA)

Bezalel Stern
Partner – Advertising, Marketing and Media Practice
Manatt, Phelps & Phillips LLP

Meghan Stoppel
Member | State Attorneys General Practice
Cozen O'Connor

Ashish Talati
Founding Member
Talati Law Firm

Eric Unis
Senior Attorney, National Advertising Division (NAD)
BBB National Programs

Heather Van Blarcom
General Counsel
Thorne

Claudia Vetesi
Partner
Morrison & Foerster LLP

Cara Welch, Ph.D.
Director, Office of Dietary Supplement Programs Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Pre-Conference Workshops

Monday, June 24, 2024

A

9:00 – 12:30

Dietary Supplement GMPs Boot Camp: A Comprehensive Deep-Dive Into Current Dietary Supplement Good Manufacturing Practices (GMPs) and Best Practices for Ensuring Compliance

Laura Najera, *Head of Regulatory,* **Americas, Metagenics**

Tara Lin Couch, Ph.D., *Owner,* **TLC Regulatory and Laboratory Consulting**

Cynthia Meyer, *Partner,* **Kleinfeld, Kaplan & Becker, LLP**

A strong working knowledge of current good manufacturing practices (GMPs) is a critical competency for dietary supplement industry stakeholders. Regulators, enforcers, and industry are sharpening their focus on supplement cGMPs to ensure the quality of these increasingly popular products. Industry uncertainty about evolving GMP standards and specific regulations have led to numerous FDA observations and Warning Letters in the last year.

This Boot Camp will provide dietary supplement companies and their counsel with a thorough understanding of 21 CFR 111 and other statutory GMP requirements which are applicable to all companies who manufacture, label, pack or hold dietary supplements for sale in the United States, including those who engage in the testing, quality control and distribution of supplements.

Topics of discussion will include:

- Breaking down 21 CFR 111: outlining the full scope of GMP regulations for dietary supplements in the United States
- Understanding the core responsibilities imposed on supplement brand owners, manufacturers, packers, labelers and holders of dietary supplements
- Practical guidance on how to apply current GMP requirements at your company/facility
- Analyzing the latest trends in FDA Form 483 observations and warning letters being issued to dietary supplement companies
  - » What are the most commonly cited issues?
- Exploring recent FDA enforcement activity against dietary supplement companies stemming from GMP violations

> *I appreciated the attention to urgent regulatory concerns, the application to personalized nutrition, and specifically — how each presenter tied it back to what companies can do to protect themselves and the industry.*
>
> – Regulatory Associate, FoodState

B

1:30 – 5:00

Social Media Claims Substantiation Master Class: Formulating a Playbook for Making Compliant Claims on Social Media in a Time of Evolving Agency Guidance

David Mallen, *Partner, Co-Chair, Advertising Disputes,* **Loeb & Loeb LLP**

Kat Dunnigan, *Attorney,* **Davis Wright Tremaine LLP**

Jennifer Fried, *Partner, Advertising Practice Lead,* **Finnegan, Henderson, Farabow, Garrett & Dunner, LLP**

Ensuring proper claims substantiation for a dietary supplement product is often a complex, fact-specific process – and one which is drawing increased scrutiny from both regulators and the plaintiff's bar alike. The changing nature of advertising with its reliance on more non-traditional marketing, such as influencers, endorsements, consumer reviews, and emerging social media platforms, presents new challenges for ensuring claims are properly substantiated.

In this workshop, we will closely examine how dietary supplement companies can effectively utilize the social media while ensuring that claims about their products are thoroughly substantiated, appropriate disclosures are made, and advertising practices are in line with the latest regulatory guidance. Topics of discussion will include:

- Determining how to compliantly promote your product and win consumer confidence while staying out of trouble with the regulators
- Examining how the latest FTC substantiation guidance, endorsement disclosure guidelines, and enforcement activity around use of consumer reviews are impacting social media and other online marketing by supplement companies
- Examining FTC's final set of revised Endorsement Guides
  - » What has changed in terms of substantiation requirements and what areas of focus are on the horizon for the Commission?
  - » What are the implications for industry?
- Understanding the implications of the FTC's new Proposed Rule on the Use of Consumer Reviews and Testimonials
- Determining the scientific evidence necessary to meet FTC claim substantiation standards
- Examining how the latest regulatory guidance and enforcement activity impacts influencers and advertisers on platforms like TikTok, Instagram stories, Snapchat, and online retailers like Amazon
- Developing best practices for:
  - » Consumer endorsements and consumer reviews
  - » Expert, celebrity, and influencer endorsements
  - » Reviews on third-party websites
  - » Repurposed reviews
  - » Disclosures of material connections to the brand or seller of the advertised product
- Influencing your influencers: preventing rogue influencers from touting unsubstantiated claims and implementing safeguards against influencer campaign liabilities

Main Conference Day 1

Tuesday, June 25, 2024

8:30

Co-Chairs Opening Remarks

Megan Olsen, *Senior Vice President & General Counsel,* **Council for Responsible Nutrition (CRN)**

Taneesha Routier, *Director of Regulatory Affairs,* **Xymogen**

8:45

Coffee & Conversation with Dietary Supplement Industry Leaders: Exploring the Top 10 Things Currently Keeping Industry Up at Night

Barbara Sanchez, *General Counsel,* **Nestlé Health Science U.S.**

Chris Reid, *Chief Legal Officer,* **Plexus Worldwide**

Anastasia Jones, *Regulatory Affairs Director,* **OLLY PBC**

Heather Van Blarcom, *General Counsel,* **Thorne**

MODERATOR: **Diane McEnroe,** *Partner,* **Sidley Austin LLP**

Key dietary supplement company leaders will share and address their top regulatory and policy concerns for this year as well as 2025. At the end of the segment, participate in an interactive Q+A that will allow you to ask your most pressing questions and add to the dialogue.

DSHEA at 30
Looking Back and Moving Forward

9:45

Examining the DSHEA of Today and Projections for the DSHEA of Tomorrow: Think Tank on Combatting Bad Actors and Fostering Responsible Industry

Taneesha Routier, *Director of Regulatory Affairs,* **Xymogen**

Miriam Guggenheim, *Partner,* **Covington & Burling LLP**

Patrick Runkle, *Senior Litigation Counsel, Consumer Protection Branch,* **U.S. Department of Justice**

- Analyzing the parts of DSHEA that have allowed the dietary supplements industry to thrive, and examining the parts of DSHEA that may be stifling innovation or putting the industry at risk
  - » What parts of DSHEA might need a present-day reset?
- Addressing inadequacies in FDA tools to handle and address bad actors in the industry
  - » What does the industry want FDA to do about chronic, flagrant law violators of DSHEA?
  - » How can FDA be given morel tools and authority to marginalize bad actors and keep dangerous products out of the market?
  - » Weighing the risks and benefits of giving FDA more authority to stifle criminal activity and the sale of fraudulent products
- Evaluating how industry can combat irresponsible actors in the absence of initiatives to do so by the FDA
  - » What types of industry initiatives already exist?
- Assessing the pros and cons of proposed legislative updates to DSHEA

10:30 Morning Break

11:00

Spotlight Interview with FDA: Assessing the Full Impact of the FDA Reorganization on the Dietary Supplements Industry and Other FDA News

Cara Welch, Ph.D., *Director, Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition,* **U.S. Food and Drug Administration**

INTERVIEWED BY: **Steve Mister,** *President & CEO,* **Council for Responsible Nutrition (CRN)**

- Understanding the full scope of implications of the creation of the Unified Human Foods Program (HFP) and New Office of Regulatory Affairs (ORA) Model
- Analyzing CRN's concerns about the proposal to include supplement oversight under a new Office of Food Chemical Safety, Dietary Supplements, and Innovation
- Examining how the new Office of Critical Foods will interact with the OFCSDSI
- Understanding what will and will not change with the agency's Reorganization
  - » Are the agency's areas of focus going to change?
  - » Will FDA supplement activity increase or decrease after the Reorganization?
  - » Could certain types of activity increase, such as inspection frequency?
- FDA insights on the agency's latest guidance and enforcement initiatives:
  - » Updates to the new dietary ingredient notification (NDIN) guidance
  - » Analyzing enforcement priorities, including inspections and keeping fraudulent products off the market
  - » Focus on manufacturing issues under scrutiny, such as ingredient overages
  - » Exploring how collaboration with CRN and FDA bolsters the industry and protects consumers

11:45

Preparing for a New Era of FDA Inspections: Navigating Impending Inspection Process Changes and Working with FDA to Increase Inspection Efficiencies

Sharon Lindan Mayl, *FDA Partner,* **DLA Piper**

Ashish Talati, *Founding Member,* **Talati Law Firm**

MODERATOR: **Haiuyen Nguyen,** *Vice President, Regulatory & Nutrition Policy,* **Council for Responsible Nutrition**

As part of the FDA's initiative to strengthen its oversight of human food, the agency is unifying inspection and compliance programs under the new Unified Human Foods Program – which includes dietary supplements. This session will explore topics, including:

- Analyzing changes to FDA inspection processes resulting from the Human Foods Program and Office of Regulatory Affairs Reorganization
  - » What will the proposed Office of Inspections and Investigations (OII) look like and how will FDA's field operations dedicated to human food change?
- Examining the latest tools and methods that FDA is using to increase inspection efficiencies
- Understanding the pros and cons of remote regulatory oversight and assessments
  - » Navigating the challenges that can arise in the use of remote inspection tools and processes
- What FDA enforcement functions are being shifted from ORA to compliance offices in FDA centers?
  - » What impact will this have on future FDA inspections and compliance actions?
- How will reorganization impact inspections and compliance programs covering international entities?
- Practical tips for handling inspections, such as getting your facility prepared for your inspections, managing responses to inspections and understanding when you might need to get outside counsel involved

12:30

FDA Activity Round-Up and Industry Discussion: Forecasts for the Future of NDIs, Healthy Claims, IND Requirements and More

Rend Al-Mondhiry, *Partner,* **Amin Wasserman Gurnani, LLP**

Jena Rostorfer, MS, RD, *Director, US/Canada Regulatory Affairs,* **Abbott**

- Lessons and takeaways from the latest trends in FDA enforcement and warning letters
- Analysis of FDA's 2024 updates to NDIN guidance and what's to come
  - » Strategies for complying with FDA's updates and anticipating changes to other parts of the NDIN guidance
- Examining the status of FDA's final rule governing "healthy" nutrient content claims
  - » Contemplating FDA's next steps and tips for preparing to comply with a final rule
- Status update on FDA's proposed amendments to regulations on Investigational New Drug applications (INDs)
  - » Analyzing the impact of recent developments on the design of clinical studies, IND requirements, and dietary supplement research

1:15 Networking Luncheon for Speakers and Delegates

The United States of Supplements

2:15

Analyzing New State Laws and Legislation Affecting Supplements: Considerations for Interstate Compliance and What Recent State Activity Could Mean for the Future of FDA Deference

Patricia Kim, *Senior Regulatory Counsel,* **Growve**

Meghan Stoppel, *Member | State Attorneys General Practice,* **Cozen O'Connor**

Paola Clavijo, *Regulatory Associate Director – Policy, Advocacy and Risk Management,* **Unilever**

- Breaking down New York's new supplement age restriction law
- Examining other newly introduced and proposed state bills placing age restrictions on the purchase of certain supplement products
- Addressing the challenges of navigating conflicting cross-state standards
- Examining the recent trend of states and local governments interest in food and supplement safety and what this means for FDA authority
  - » Overview of other state legislation that would impose additional restrictions on food and supplement practices, such as state ingredient bans and sustainable packaging laws
- Analyzing how industry can combat emerging state-level restrictions on the supplement industry: battling the narrative that the FDA does not have appropriate authority to deal with the purported harms targeted by state legislation and laws
  - » Would a national standard be preferrable in certain situations and what would that look like?
  - » Should industry support efforts for additional FDA authority to minimize state activity?

Spotlight on Dietary Supplements Litigation

3:15

Examining the Latest Class Action Activity Posing Threats to the Dietary Supplements Industry

Christine Burdick-Bell, *Vice President & General Counsel,* **Pharmavite LLC**

Lori Leskin, *Partner, Co-Chair, Consumer Products Practice Group,* **Arnold & Porter**

- Analyzing the latest trends in class action activity impacting the dietary supplements space
  - » Examining the latest advertising and labeling practices triggering class action claims
  - » Identifying key lessons and takeaways from the latest litigation activity
  - » Insights on what the plaintiff's bar may target next
- Assessing how current class action activity will impact future labeling and marketing practices as well as your bottom line
- Identifying new and continuing class actions risks:
  - » Technical label compliance, such as calorie calculations, net contents statements, DSHEA disclosure placement
  - » Ingredients for which safety has been questioned, such as titanium dioxide and PFAS
  - » Reemergence of slack fill cases
  - » "Green" claims and other claim categories at highest risk for class actions

> *I appreciated the attention to urgent regulatory concerns, the application to personalized nutrition, and specifically — how each presenter tied it back to what companies can do to protect themselves and the industry.*
>
> – Regulatory Associate, FoodState

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

4:00 Afternoon Break

4:15

Formulating Strategies for Insulating Yourself from Class Action Litigation: How to Think Like a Plaintiff's Attorney

Claudia Lewis, *Partner,* **Venable**

Veronica Colas, *Partner,* **Hogan Lovells LLP**

- Designing thorough internal class action prevention and preparedness protocols
- Understanding how offensive strategies such as sound advertising claims substantiation practices can be your best defense and nip a class action in the bud
- Tracking government and consumer protection group enforcement activity on which the plaintiff's bar might try to piggy-back
- Predicting when you may be a class action target and developing pre-suit defense strategies

5:00

Ingredient Overages in Dietary Supplements: The Latest Compliance Concerns, Litigation Risks and Best Practices to Ensure Products Contain Declared Values Throughout Shelf-Life

Claudia Vetesi, *Partner,* **Morrison & Foerster LLP**

Mohamed Koroma, *Director, R&D,* **Pharmavite**

Ingredient overage practices are drawing increasing attention from consumer products testing labs, the media and the plaintiffs' bar. This panel will discuss:

- The latest legal, compliance and litigation concerns surrounding ingredient overage practices
- The regulatory and marketing considerations related to ingredient overages
- Industry best practices that can help ensure consumer safety and consumer confidence
  - » Analyzing best practices for manufacturing and labeling to avoid risks associated with product degradation and claims related to overages
  - » Strategies for reducing your overages
  - » Tips for changing or improving the messaging around ingredient overages

5:45 Conference Adjourns for the Day

Main Conference Day 2

Wednesday, June 26, 2024

8:30

Co-Chairs Welcome Back

8:45

Fireside Chat with the Federal Trade Commission

Christine DeLorme, *Attorney, Division of Advertising Practices,* **Federal Trade Commission**

INTERVIEWED BY: **Megan Olsen,** *Senior Vice President & General Counsel,* **Council for Responsible Nutrition (CRN)**

9:15

Critical Takeaways from the Latest Dietary Supplement Advertising Decisions Issued by the National Advertising Division (NAD)

Eric Unis, *Senior Attorney, National Advertising Division (NAD),* **BBB National Programs**

Katie Bond, *Partner,* **Keller & Heckman LLP**

In this session, the National Advertising Division (NAD) will join industry leaders in examining key dietary supplement advertising decisions issued over the course of the last year. Tune in to gain insights on what supplement advertising claims and practices are raising red flags with regard to green claims, health claims, endorsements, consumer reviews and beyond. Explore how the NAD has incorporated changes to the FTC's guidance for health-related claims into their decision-making process. Walk away with an understanding of the latest advertising "watch outs" – and best practices for how to avoid them.

10:00 Morning Coffee Break

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

10:30

AI in the World of Dietary Supplement Advertising: Preparing for the Next Frontier of Ad Claims Scrutiny and Enforcement

Bezalel Stern, *Partner – Advertising, Marketing and Media Practice,* **Manatt, Phelps & Phillips, LLP**

Candice Kersh, *Partner – Advertising, Marketing, and Public Relations Group,* **Frankfurt Kurnit Klein & Selz**

- Analyzing the latest ways that generative AI models are being used in dietary supplement ad campaigns
- Examining the legal and compliance risks of using AI chat bots to generate ad ideas and content for supplement marketing (e.g. ChatGPT, Google Bard, etc.)
  - » Understanding how to sufficiently document the creative process used to create ads when using AI
- Identifying the risks of using computer-generated "virtual influencers" to connect with followers and sway consumer purchase decisions
  - » Assessing the FTC's recent focus on virtual influencers engaged in "review hijacking"
  - » Understanding how virtual influencers can legally push a product while providing sufficient disclosures and information to the consumer

11:15

Managing the Latest Threats to the Dietary Supplement Industry Coming From Emerging Contaminants

Seth Mailhot, *Partner,* **Husch Blackwell**

Aliza Karetnick, *Partner,* **Morgan Lewis & Bockius LLP**

- Examining the latest state legislative efforts to ban contaminants in food products and understanding the implications on the supplements industry
  - » Understanding what ingredients are currently being scrutinized by legislators, plaintiff's counsel, consumer advocates, and other relevant stakeholders
- Analyzing recent purported harmful ingredient class actions being brought across the food and supplements industry
  - » Exploring common themes, allegations and takeaways
- How supplement companies and their counsel should be reviewing product formulations, label claims, and other company statements to mitigate litigation risks
- Assessing the latest PFAS laws, legislation and litigation impacting the dietary supplements industry at the federal and state levels
  - » PFAS in packaging
  - » Product labeling and disclosures
  - » Bans on the intentional addition of PFAS
  - » Thresholds for the unintentional addition of PFAS

12:00

Health Claims Substantiation in the Aftermath of Last Year's FTC Guidance: Lessons Learned from Major Cases, FTC Actions, and CRN Advocacy in the Past Year

Geoffrey Castello, *Partner,* **Kelley Drye & Warren**

Susan Hewlings, *Vice President of Research Affairs,* **Radicle Science**

- FTC's Health Products Compliance Guidance one year later: examining the latest developments impacting health claims made by the supplements industry
- Analyzing the recent *Quincy* verdict and its implications
  - » How could the outcome change the FTC's guidance position?
  - » What can industry learn from *Quincy* in light of their own substantiation practices?
- Exploring the role that clinical trials play in the substantiation of health-related claims
  - » Understanding clinical trial practices in light of the heightened FTC guidance and FTC and NAD precedent from the past year
- Using IP in substantiation to bolster a company's position
  - » Cornering the market on an ingredient through IP protections

12:45

Regulation by Retailer: Understanding the Latest Testing and Labeling Requirements of Dietary Supplement Retailers

Allyn Shultis, *Executive Director,* **Global Retailer and Manufacturer Alliance (GRMA)**

Brandi Reinbold, *Senior Manager, Technical, Global Health Sciences Certification,* **NSF International**

Over the past decade, retailers like Amazon and major drug store and grocery chains have imposed their own product testing and manufacturer quality controls on dietary supplement products. This panel will analyze the latest retailer requirements, efforts to harmonize those requirements, and the latest initiatives taken to have industry quality standards recognized by FDA. Topics of discussion include:

- Understanding the various, complex retailer requirements that supplement companies must comply with to sell their products
- Exploring how to overcome the challenges and burdens that current retailer requirements are placing on internal R+D, quality assurance and other manufacturing processes
- Examining the latest efforts of GRMA to develop and sustain harmonized quality and safety standards, GMPs, and certification programs for dietary supplements
- Looking at prior times when the FDA has recognized third-party quality standards
  - » Using these examples as a roadmap for achieving FDA recognition of dietary supplement third-party standards

1:30 Conference Ends

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.

– Regulatory Associate, FoodState

I really enjoyed the ability to interact, converse and network with the speakers as well as the other attendees to discuss their experiences and knowledge in these areas of the Supplements industry. The wide range of topics and knowledge was impressive.

– Paralegal, Vitaquest

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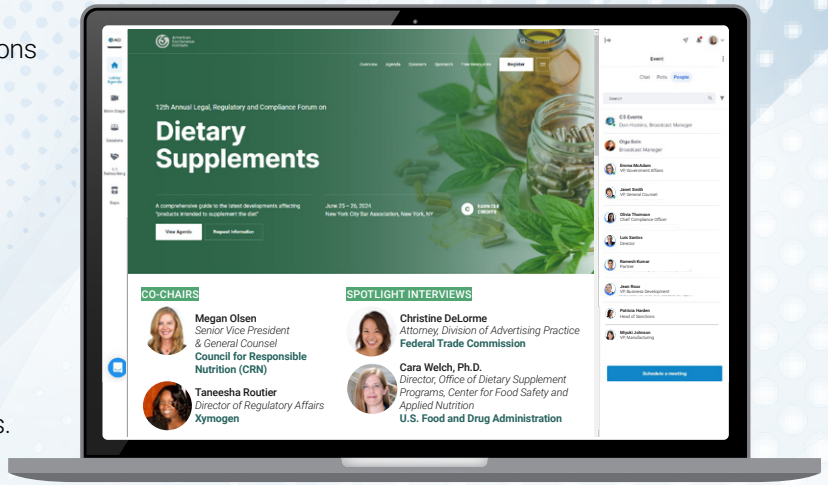
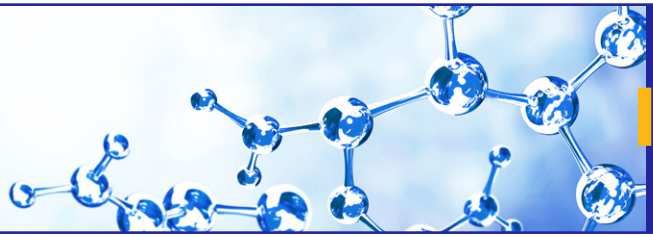


UPCOMING EVENT

ACI's Summit on

PFAS

Regulation, Compliance, and Litigation



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Venue Information

New York City Bar Association
42 West 44th Street, New York, NY

Hotel Information

Sofitel Hotel
45 West 44th Street, New York, NY 10036
Reservations: 212-235-8844

BOOK NOW

Please note that when the room block fills, guestroom availability and rate can no longer be guaranteed.

Book with confidence!

Register and pay to lock in your early rate and be eligible for a full refund until June 11, 2024.

If you are unable to attend for any reason, you will have the following options:

- A full credit note for you, or a colleague to attend another event.
- A full refund.

All cancellations and changes must be submitted to CustomerService@AmericanConference.com by June 11, 2024.

3 Ways to Register

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SAVE $100

PRICING	Register & Pay by May 3, 2024	Register & Pay after May 3, 2024
In-Person Conference	$2495	$2595
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Workshops: A – Dietary Supplement GMPs Boot Camp B – Social Media Claims Substantiation Master Class	$600 each	

All program participants will receive an online link to access the conference materials as part of their registration fee.
Additional copies of the Conference Materials available for $199 per copy.

REGISTRATION CODE:
B00-669-669L24.WEB

CONFERENCE CODE:
669L24-NYC

Bringing a Team?*	
1–3	No Discount
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12+	Call 888-224-2480

Special Discount

ACI offers financial scholarships for government employees, judges, law students, non-profit entities and others. For more information, please email or call customer service.

**Team/group registrations must be from the same organization/firm and register together in one transaction.*

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