ACI American Conference Institute

In Collaboration with the

Council for Responsible Nutrition
The Science Behind the Supplements

EARN CLE CREDITS

ACI's 7th Annual Legal, Regulatory and Compliance Forum on

DIETARY SUPPLEMENTS

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

June 18–19, 2019 | The InterContinental New York Times Square | New York, NY

Distinguished Co-Chairs:

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

Steve Mister
President & CEO
Council for Responsible Nutrition

Keynote Address:

Cara Welch, Ph.D.
Acting Special Assistant to the Deputy Commissioner for Policy, Legislation, and International Affairs
Office of the Commissioner
U.S. Food and Drug Administration

Insights from:

GOVERNMENT

U.S. Food & Drug Administration

U.S. Federal Trade Commission

CONSUMER AND RETAILER ORGANIZATIONS AND ASSOCIATIONS

American Herbal Products Association

Global Retailer and Manufacturer Alliance

National Advertising Division — Advertising Self-Regulatory Council

KEY INDUSTRY STAKEHOLDERS

Atrium Innovations

Care/of

Garden of Life, LLC

Metagenics, Inc.

Nature's Bounty Co

Nature's Way Brands

New Chapter, Inc.
(A Procter & Gamble Subsidiary)

Pharmavite LLC

RB Health

Media Partner: WholeFoods Magazine

Register Now | AmericanConference.com/DietarySupplements | 888 224 2480

a C5 Group Company
Business Information in a Global Context

Be part of the leading forum which helps the dietary supplement industry chart its course through the new challenges of the day.

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.

Dear Colleague:

The dietary supplement industry is living through interesting times, to say the least. In mid-February, FDA Commissioner Scott Gottlieb announced the agency would be initiating "one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years." Ironically, less than three weeks later, Commissioner Gottlieb announced his resignation, leaving the industry wondering how the status of the FDA's Dietary Supplement Working Group would survive that transition at FDA — not to mention these proposed changes in regulatory modernization and oversight and the future of DSHEA.

The fate of other urgent priorities under Dr. Gottlieb's tenure also hang in the balance. His call for a mandatory product registry and FDA's promise to find a legal pathway to market for hemp-derived CBD will outlast his tenure, leaving stakeholders to ponder FDA's next move on these matters.

At this year's conference, we will explore the status of these developments at FDA, as well as challenges presented by retailer-imposed requirements for the supplements they sell, China trade wars and tariffs, personalized supplement regimens, probiotics, new supplement business models from e-commerce to the practitioner-only market, and the commercial implications for social media marketing. We will also examine how these developments are working to strengthen or hinder the growth of this industry.

ACI and **CRN** have designed this year's agenda to reflect the impact these developments will have on your business while also providing the state of the industry updates and opportunities for networking and discussion which you have come to expect.

Register today for the industry's premier and most comprehensive legal, regulatory and compliance forum on dietary supplements by calling 1-888-224-2480, or visiting us online.

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

Very truly yours,

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

Jeff Brams
GC, & VP R&D and Regulatory
Garden of Life, LLC (West Palm Beach, FL)

Christine Burdick-Bell
Vice President & General Counsel
Pharmavite LLC (West Hills, CA)

Richard Cleland
Assistant Director,
Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission (Washington, DC)

Tara Lin Couch, Ph.D.
Senior Directory of Dietary Supplements and Tobacco Services
EAS Consulting Group (Alexandra, VA)

Kat Dunnigan
Senior Staff Attorney
National Advertising Division
Advertising Self-Regulatory Council (New York, NY)

Tara Falsani
Vice President and General Counsel
Nature's Way – Schwabe North America (Minneapolis, MN)

Gregory W. Fortsch
Associate General Counsel for Regulatory Affairs & Privacy Officer
The Nature's Bounty Co. (Ronkonkoma, NY)

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

Randy King, DVM, PhD
Chief Science Officer
New Chapter, Inc. (A Procter & Gamble Subsidiary) (Brattleboro, VT)

Paul E. Konney
Executive Vice President, General Counsel and Head of Global Regulatory Affairs
Metagenics, Inc. (Aliso Viejo, CA)

Riëtte van Laack, Ph.D.
Director
Hyman, Phelps & McNamara, P.C. (Washington, DC)

Claudia A. Lewis
Partner
Venable LLP (Washington, DC)

Mark Brian Levine
Associate General Counsel
RB Health (Parsippany, NJ)

Diane C. McEnroe
Partner
Sidley Austin LLP (New York, NY)

Michael McGuffin
President
American Herbal Products Association (Silver Spring, MD)

Cynthia L. Meyer
Partner
Kleinfeld, Kaplan & Becker, LLP (Washington, DC)

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

Diana Morgan, MS
Head of Scientific & Regulatory Affairs
Care/of (New York, NY)

Trenton H. Norris
Partner
Arnold & Porter Kaye Scholer LLP (San Francisco, CA)

Jessica P. O'Connell
Partner
Covington & Burling LLP (Washington, DC)

Megan Olsen
Assistant General Counsel
Council for Responsible Nutrition (Washington, DC)

John Packman
Of Counsel
DLA Piper LLP (US) (Atlanta, GA)

Stuart M. Pape
Shareholder, Chair FDA Practice
Polsinelli (Washington, DC)

Laura Siegel Rabinowitz
Special Counsel
Kelley Drye & Warren LLP (New York, NY)

Barry W. Ritz, P.h.D
Vice President and Chief Scientific Officer, Professional R&D and Regulatory
Atrium Innovations (Kennett Square, PA)

Paul D. Rubin
Partner
Debevoise & Plimpton LLP (Washington, DC)

Randal M. Shaheen
Partner
Baker & Hostetler LLP (Washington, DC)

Randy Slikkers, MBA
Executive Director
Global Retailer and Manufacturer Alliance (GRMA) (Washington, DC)

Frederick A. Stearns
Partner
Keller and Heckman LLP (Washington, DC)

Ashish R. Talati
Partner
Amin Talati Upadhye, LLP (Chicago, IL)

Cara Welch, Ph.D.
Acting Special Assistant to the Deputy Commissioner for Policy, Legislation, and International Affairs
Office of the Commissioner U.S. Food and Drug Administration (College Park, MD)

EARN CLE CREDITS — Continuing Legal Education Credits

Accreditation will be sought in those jurisdictions requested by the registrants which have continuing education requirements. This course is identified as nontransitional for the purposes of CLE accreditation.

ACI certifies that the activity has been approved for CLE credit by the New York State Continuing Legal Education Board.

ACI certifies that this activity has been approved for CLE credit by the State Bar of California.

You are required to bring your state bar number to complete the appropriate state forms during the conference. CLE credits are processed in 4-8 weeks after a conference is held.

ACI has a dedicated team which processes requests for state approval. Please note that event accreditation varies by state and ACI will make every effort to process your request.

Questions about CLE credits for your state? Visit our online CLE Help Center at www.americanconference.com/CLE

Day One
Tuesday, June 18, 2019

"Comprehensive and in-depth review of leading regulatory issues for the dietary supplement industry."

Chad Lewis, Chief Operating Officer, Universal Nutrition

7:15 | Continental Breakfast and Registration

8:15

Co-Chairs' Welcoming Remarks

Scott Bass
Partner
Sidley Austin LLP (New York, NY)

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

8:30

The Dietary Supplement Industry's State of the Union: How Regulations and Regulators are Addressing the Industry 25 Years After DSHEA

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

Since we last met in 2018, the dietary supplement industry has encountered both new and ongoing legal, regulatory, and compliance challenges. DSHEA will enter its 25th year and the industry continues to ponder its evolution in the current climate, as regulators at both the state and federal level assess whether they have the tools to stop bad actors and keep consumers safe. Continued innovation and increased interest in different types of ingredients, such as the use of hemp and the ever-growing popularity of probiotics, pose their own set of unique challenges. Further, the FDA has still not issued a final NDI Draft Guidance leaving matters of new ingredients classification unresolved. Questions also remain as to the correct usage of the word "natural" in the absence of a proper agency definition.

In this session, Steve Mister will discuss these and many of the other challenges the industry is facing as he presents his state of the union.

9:00

Debating the Risks and Benefits of a Mandatory Product Registry

Scott Bass
Partner
Sidley Austin LLP (New York, NY)

The idea of a mandatory product registry has invited significant debate in recent years. Presently, there is no federal mandate that directs dietary supplement manufacturers to register their products, but with recent FDA interest in this topic, the time may have come for industry to take a stand. With CRN's OWL now in its third year, we see that the voluntary product registry system is working quite well, thus, begging the question of whether a federally mandated registry is necessary. However, as has been the case with many other industries, voluntary systems often pave the way for mandatory ones.

In this session, our speakers will explore the FDA's position, Congress' perception, and industry's thoughts with respect to a mandatory registry. Points of discussion will include:

- Examining FDA's position on a mandatory product registry in light of the public meeting that FDA intends to hold in Spring 2019 and recent statements from former Commissioner Gottlieb signaling support for a registry
- Assessing the impact of CRN's OWL and whether voluntary product registration is effective vs. mandatory product registration
- Identifying problems that a registry would be designed to solve and assessing whether a registry would actually be effective at solving these problems
- Analyzing mechanisms that would make a registry both effective and ease compliance burdens on industry

TABLETOP EXERCISE
NEW this year, an interactive session for audience engagement and knowledge sharing

To further add to the debate, attendees will have a chance to share insights with fellow attendees. We will address the pros and cons of creating a mandatory registry vs. voluntary self-policing standards, as well as discuss mechanisms that could make a registry work for both FDA and industry. In this tabletop exercise, leaders will pose questions and guide the discussion. At the end of the tabletop exercise, we will discuss the findings.

10:15 | Morning Coffee Break

10:30

Keynote Address

Cara Welch, Ph.D.
Acting Special Assistant to the Deputy Commissioner for Policy, Legislation, and International Affairs
Office of the Commissioner
U.S. Food and Drug Administration (College Park, MD)

11:00

FOCUS ON CHINA: Understanding the Far-Reaching Implications of Tariffs and Trade Wars

Laura Siegel Rabinowitz
Special Counsel
Kelley Drye & Warren LLP (New York, NY)

At the end of 2018, the U.S. Trade Representative implemented a 90-day trade truce with China, delaying a proposed 25 percent tariff on China imports until March 1, 2019. The present tariff remains at 10 percent and at time of press it remains to be seen if the 25 percent tariff will take effect. While this tariff is impacting many industries, its effect on the dietary supplement industry may be significant with many of its prime raw ingredients such as Vitamin C coming directly from China.

This session will explore the challenges associated with doing business in China and examine ways companies can reduce the impact of trade wars on their business.

- Understanding the array of customs, international trade, and tariff laws associated with China
- Adjusting business models and plans in the wake of increased tariffs, such as the challenges associated with new equipment purchases or cost of raw ingredients in the wake of tariff increases
- Addressing ways companies may be exempt from the tariffs imposed on its products
- Analyzing challenges with sourcing products from other countries if tariff increases make doing business with China too costly
- Anticipating how retaliatory action could affect product imported into China

12:00 | Networking Luncheon for Speakers and Attendees

1:00

REGULATION BY RETAIL: Assessing the Challenges of Complying with Retailer-Imposed Quality Standards

Randy Slikkers, MBA
Executive Director
Global Retailer and Manufacturer Alliance (GRMA) (Washington, DC)

In light of increased scrutiny from regulators and consumers, retailers are increasingly imposing their own standards and checks on dietary supplement companies' compliance with regulatory requirements. These standards range from testing programs to manufacturing facility audits and other mechanisms designed to ensure supplements sold by retailers are safe and compliant. In this session, we will hear from individuals that are helping to design these standards and those that are helping companies navigate these programs. Panelists' discussion will include the following and more:

- Addressing the phenomenon of retailers requiring supplement manufacturers to adhere to a new set of private testing standards as a precursor to product placement on store shelves
- Overcoming compliance challenges when testing standards between retailers differ
- Assessing the impact of the Supplement Safety and Compliance Initiative (SSCI) led by Walmart and GNC, and new ANSI-accredited auditing standards developed in collaboration with the Global Retailer and Manufacturer Alliance (GRMA)
- Discussing how retailers and standard-setting bodies can collaborate to harmonize standards and reduce burdens on industry

2:00

Clarifying the Legal Pathway for Hemp-Derived CBD in Food and Dietary Supplements

Richard Cleland
Assistant Director, Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission (Washington, DC)

Cynthia L. Meyer
Partner
Kleinfeld, Kaplan & Becker, LLP (Washington, DC)

Megan Olsen
Assistant General Counsel
Council for Responsible Nutrition (Washington, DC)

Ashish R. Talati
Partner
Amin Talati Upadhye, LLP (Chicago, IL)

Despite the FDA's position that hemp-derived CBD cannot be used as a food or supplement ingredient, consumer demand and the market for CBD products continues to grow. The passage of the 2018 Farm Bill, however, is forcing the agency to re-examine this position and may lead to a new pathway of acceptance.

- Understanding FDA's current position on hemp-derived CBD in dietary supplements and food
- Examining the use of hemp-derived CBD in dietary supplements after passage of the 2018 Farm Bill
- Analyzing hemp production by state and evaluating current state regulations governing these activities
- Assessing pathways open to FDA and industry to develop a legal market for CBD in dietary supplements and food
- Anticipating the next steps if a legal pathway for CBD is established for foods and dietary supplements, *e.g.*, cGMP's, testing, claims substantiation

3:00 | Afternoon Refreshment Break

3:15 INTERACTIVE SESSION – CASE STUDY

Coattails, Master Files, and NDIs

Tara Lin Couch, Ph.D.
Senior Directory of Dietary Supplements and Tobacco Services
EAS Consulting Group (Alexandra, VA)

Paul D. Rubin
Partner
Debevoise & Plimpton LLP (Washington, DC)

Frederick A. Stearns
Partner
Keller and Heckman LLP (Washington, DC)

As FDA continues to develop its NDI guidance in preparation for final guidance, important questions have been raised about how an NDI system can be created that protects industry investment in new dietary ingredient development, while still ensuring access to ingredients for manufacturers and consumers. Panelists will discuss these challenges, including:

- Analyzing the latest statements and activities from FDA with regard to NDI systems and guidance that would help protect the manufacturers' significant investment in developing new dietary ingredients
- Comparing similarities with FDA's proposals for NDIs to similar proprietary systems enforced by FDA, such as drug exclusivity and Food Contact Notifications
- Exploring mechanisms for FDA enforcement of such a system

Day Two
Wednesday, June 19, 2019

4:15

From "GMO" to "Natural" and Everything in Between – Insights on New Label Requirements

Jeff Brams
GC, & VP R&D and Regulatory
Garden of Life, LLC (West Palm Beach, FL)

Stuart M. Pape
Shareholder, Chair FDA Practice
Polsinelli (Washington, DC)

In the last few years, the dietary supplement and functional food industries have seen a flurry of activity around labeling requirements. From new Nutrition and Supplement Facts requirements, to labeling for bioengineered food, and continued uncertainty around the definition for terms like "natural" and "healthy", manufacturers have their plates full with ensuring their products meet the new requirements and don't run afoul of old requirements. As a final panel for Day One, speakers will explore and help companies navigate these challenges.

- Examining the status of the new Supplement and Nutrition Facts labeling requirements, and assessing whether your company is ready for the compliance deadlines
- Understanding new regulations requiring labeling for bioengineered foods
- Analyzing the use of claims with ambiguous or changing definitions, such as "natural" and "healthy", as well as interpreting FDA's current position on these terms
- Exploring the latest class action cases that target label claims
  - » Navigating the risk of using this term

5:00 | Conference Adjourns to Day Two

7:15 | Continental Breakfast

8:15

Conference Co-Chairs' Welcoming Remarks and Recap of Day One

8:30

PROBIOTICS: Understanding the Unique Legal Challenges Posed by this Distinct and Booming Category of Microorganisms

Randy King, DVM, PhD
Chief Science Officer
New Chapter, Inc. (A Procter & Gamble Subsidiary) (Brattleboro, VT)

Riëtte van Laack, Ph.D.
Director
Hyman, Phelps & McNamara, P.C. (Washington, DC)

- Examining the recent trends associated with the use of probiotics in the dietary supplement space
- Addressing controversies surrounding the science behind the claims, such as unraveling the substantiation challenges associated with the use of live organisms and understanding the correlation, if any, with probiotics and brain health
- Providing transparency with ingredients and quality of materials with different products on the market
- Understanding FDA's current labeling requirements for probiotics and challenges created by FDA guidance on probiotic labeling
- Interpreting how *In re Bayer Phillips Colon Health Probiotics Sales Litigation* and other probiotic legal challenges effect the type of substantiation needed for probiotic claims
- Analyzing unique compliance challenges associated with probiotics, such as transportation, storage, and compliance with Supplement Facts label claims

9:30

Growing Class Actions on Product Claims — Exploring Industry Efforts to Tame the Beast

Tara Falsani
Vice President and General Counsel
Nature's Way – Schwabe North America (Minneapolis, MN)

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

John Packman
Of Counsel
DLA Piper LLP (US) (Atlanta, GA)

> *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

- Examining new class action developments that affect the dietary supplement industry
- Interpreting recent Ninth Circuit court decisions involving the burden of proof in false labeling claims
- Examining the similarities and differences in standards used for a private litigant vs. a public regulatory such as the FTC
- Analyzing strategies that companies and attorneys can use to manage class action risk

10:30 | Morning Coffee Break

10:45

Intersection of Science and the Law: How to Develop and Evaluate Clinical Studies for Claim Substantiation

Richard Cleland
Assistant Director, Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission (Washington, DC)

Kat Dunnigan
Senior Staff Attorney, National Advertising Division
Advertising Self-Regulatory Council (New York, NY)

Gregory W. Fortsch
Associate General Counsel for Regulatory Affairs & Privacy Officer
The Nature's Bounty Co. (Ronkonkoma, NY)

- Assessing what the FTC is looking for when studies are evaluated for claim substantiation
  - » Population and participants
  - » Data and outcomes measured
  - » Ingredient dose and formulation
- Developing proper research methodologies to substantiate claims
- Examining how practitioners can assess the clinical study early on in the research process
- Interpreting recent FTC enforcement actions where the clinical study did not support the claim being made
- Reviewing marketing materials to ensure the claims are properly substantiated and supported by the clinical study

11:45

Certificates of Free Sale: A Guide to Proper Issuance and Export Success

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

- Adhering to the laws of the imported and exported country to ensure products are exported without any roadblocks
- Gaining insights on certificates of free sale to ensure your product can be exported
- Different issuing jurisdictions (federal, state, city, other), and the best option for your particular situation
- Overcoming barriers when the foreign country requires additional requirements
- Understanding how multiple forms are issued by FDA CFSAN

12:15 | Networking Luncheon for Speakers and Attendees

1:15

The Rise of E-Commerce and Direct-to-Consumer Marketing: Exploring Benefits, Risks and Legal Exposures

Randal M. Shaheen
Partner
Baker & Hostetler LLP (Washington, DC)

With the proliferation of on-demand entertainment options, online social platforms, and myriad of other ways in which content reaches consumers, companies must engage in creative strategies to market products. Direct-to-consumer marketing via social media outlets, including podcasts, Facebook, Instagram, and other platforms has revolutionized the way that dietary supplements are being sold. This new way of doing business has changed the face of traditional retail as well, as the message is delivered quickly and the rise of e-commerce allows consumers to instantly purchase advertised product.

In this session, speakers will explore the nuances of e-commerce and direct-to-consumer marketing via social media and other outlets.

Points of discussion will include:

- Exploring compliance models to ensure direct-to-consumer marketing is truthful and not misleading
  - » Assessing challenges when marketing content disappears quickly and posts are deleted within a day
  - » Making effective disclosures in space-limited platforms
  - » Developing compliance plans that will provide marketing teams with flexibility to react quickly but legally to address an ever-changing marketplace
- Identifying and addressing other key legal challenges associated with social media and e-commerce programs
  - » Having an effective contracts in place with endorsers
  - » Understanding trademark and intellectual property considerations, and unique requirements for paid endorsers
- Analyzing the FTC's and FDA's policies and enforcement actions on direct-to-consumer marketing via social media outlets
- Examining how retailers and multilevel marketers in the supplement space are adapting to compete with the direct-to-consumer business models

2:00 CASE STUDY

Personalization of Dietary Supplements to Fit Consumers' Needs: Utilizing Technology and Ensuring Compliance

Paul E. Konney
Executive Vice President, General Counsel and Head of Global Regulatory Affairs
Metagenics, Inc. (Aliso Viejo, CA)

Diana Morgan, MS
Head of Scientific & Regulatory Affairs
Care/of (New York, NY)

Jessica P. O'Connell
Partner
Covington & Burling LLP (Washington, DC)

Through "personalization", supplement manufacturers are able to create customized, tailored products designed to fit specific individual health and lifestyle needs such. This new trend is becoming popular with consumers, many of whom reject the "one-size fits all" approach to products and are now accustomed to receiving personal health information, through genetic testing kits and other individualized health products. Coupled with the use of technology, the personalization of dietary supplements is the new way to target specific age groups, dietary needs, and lifestyle choices.

In this session, our speakers will address the "ins and outs" of personalization of dietary supplements to ensure your company is ready to meet the legal, regulatory, and compliance challenges, including advertising compliance, privacy, HIPPA, and more.

2:45 | Afternoon Refreshment Break

3:00

CALIFORNIA – Land of the Regulated: Prop 65, Slack Fill, and Other Significant California Regulations for the Dietary Supplement Industry

Michael McGuffin
President
American Herbal Products Association (Silver Spring, MD)

Trenton H. Norris
Partner
Arnold & Porter Kaye Scholer LLP (San Francisco, CA)

- Examining new Prop 65 ingredients affecting dietary supplements
- Addressing new Prop 65 warning regulations that went into effect in 2018 and compliance challenges a year later
- Devising internal protocols and compliance programs to ensure you are meeting Prop 65 requirements
  - » How proposed changes to OEHHA regulations could affect your compliance programs
  - » Advising on new enforcement actions related to violations of Prop 65
- Examining the California slack fill law – the most detailed in the nation -- and its impact in the industry
- Understanding competing considerations of packaging efficiency, anti-pilfering, and retailer concerns
- Adhering to California-specific requirements regarding disclosures and consumer consent for subscription-based programs
- Analyzing legislative proposals on single use plastics, packaging, fragrance disclosures, etc.

3:45 CASE STUDY

Marketing Supplements Through Healthcare Practitioners: Evaluating Business Opportunities and Potential Legal Risks

Claudia A. Lewis
Partner
Venable LLP (Washington, DC)

Barry W. Ritz, P.h.D
Vice President and Chief Scientific Officer, Professional R&D and Regulatory
Atrium Innovations (Kennett Square, PA)

At our last legal conference, we discussed the concept of supplement manufacturers marketing and distributing their products through healthcare providers. Now, one year, later we will explore the opportunities and risks of this business model through an interactive case study.

Points of discussion will include:

- Determining the extent to which the medical community has embraced this model
  - » MDs vs. DNMs
- Studying the success of manufacturer models based solely on "direct to physician" business model
- Evaluating success and revenue streams for both the physician and manufacturer
- Assessing risks and liabilities
- Analyzing whether a safe harbor exists in the learned intermediary doctrine

4:30 | Conference Ends

Post-Conference Workshops

Thursday, June 20, 2019

A

9:00 AM – 12:00 PM (Registration Begins at 8:30 am)

International Commercialization of Dietary Supplements: Compliance with Legal and Regulatory Obligations in the Trump Era

China trade wars, the fate of NAFTA, and Brexit will all have a profound effect on international business, imports, and exports. The dietary supplement industry is not immune to these international challenges.

As such, dietary supplement manufacturers must have at the very least a working knowledge of product commercialization in international markets, as well as the various laws, treaties, and tariffs that control and influence trade.

In this master class, our speakers will help you understand how to commercialize your product in foreign markets while remaining compliant with applicable laws, customs, tariff, and international trade regulations. Our workshop speakers will help you understand this market and ensure you are prepared for a successful entry.

Points of discussion will include:

- Preparing strategies and devising plans for product entry into foreign countries
- Analyzing applicable treaties, tariffs, and international trade laws to ensure compliance
- Understanding the foreign registration process and applicable agencies in different countries to ensure the product can be introduced into the foreign market
- Preparing for premarket approval and notification systems
- Assessing commercial viability for dietary supplements in the foreign market

B

1:00 PM – 4:00 PM (Registration Begins at 12:30 pm) INTERACTIVE FORMAT

Claims Substantiation Master Class

Christine Burdick-Bell
Vice President & General Counsel
Pharmavite LLC (West Hills, CA)

Mark Brian Levine
Associate General Counsel
RB Health (Parsippany, NJ)

Diane C. McEnroe
Partner
Sidley Austin LLP (New York, NY)

Claims substantiation remains an important issue for the dietary supplements industry. Not only must practitioners steer clear of disease claims, but they must also ensure that claims are adequately substantiated in an environment where the level of appropriate substantiation can be uncertain and frequently challenged by regulators and consumers. Consumer watch dog groups, enforcement agencies, and the plaintiffs' bar are always on the prowl for false advertisement of claims.

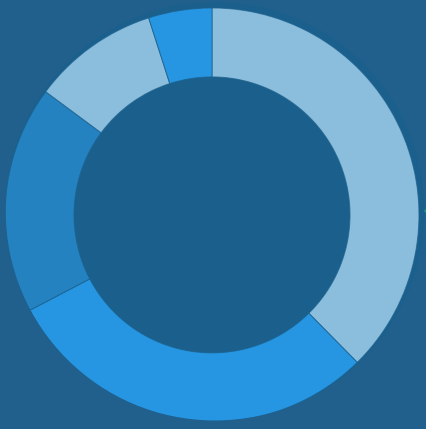
In the post-*Bayer,* now *Prevagen* era, the dietary supplements industry must be able to meet the current demands of claims substantiation. Ensure your dietary supplement products' claims are fully compliant by devising programs that cover all aspects of advertising and media.

Points of discussion will include:

- Crafting a compliance program to ensure claims are fully substantiated
- Understanding the scientific evidentiary support needed to ensure claims are supported
- Evaluating clinical study data interpretation and how results apply to your claims
- Identifying implied claims and their hidden dangers
- Review of promotional activities and claims across various media outlets and social media platforms that have raised red flags with government enforcers and consumer watchdogs

** Lunch provided for speakers and attendees for Post-Conference Workshops A & B*

Network with Key Industry Stakeholders from the Following Functions:



38% LEGAL

30% REGULATORY

18% COMPLIANCE / QUALITY

10% GOVERNMENT AFFAIRS

5% MISC.

Who You Will Meet?

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

SAVE $200

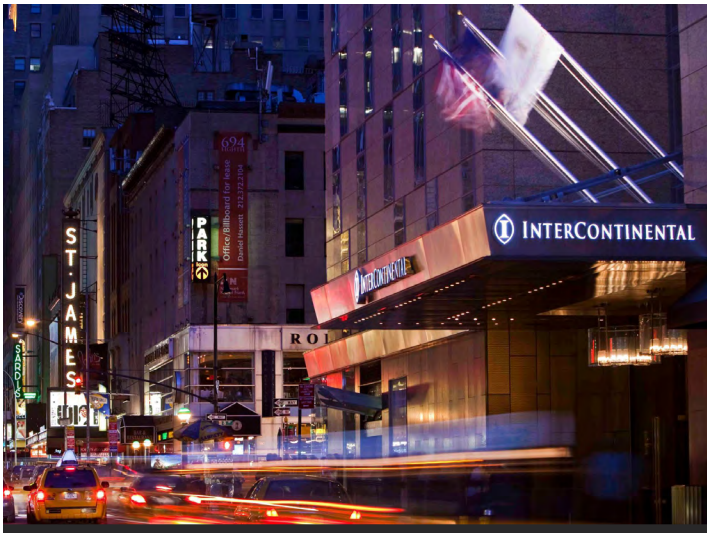
WHEN YOU BOOK BY MAY 17, 2019

Don't forget to add workshops to complete your conference experience

VISIT:
AmericanConference.com/DietarySupplements

CALL:
888-224-2480

EMAIL:
CustomerService@AmericanConference.com



Venue:

Book your room now and SAVE!

Hotel: InterContinental New York Times Square

Address: 300 West 44th Street, New York, NY 10036

Telephone: 212-803-4586

Online: AmericanConference.com/DietarySupplements/Venue

American Conference Institute is pleased to offer our delegates a limited number of hotel rooms at a negotiated rate. To take advantage of these rates, please contact the hotel's Reservations Department at 212-803-4586 and quote "ACI's Annual Dietary Supplements".

Please note that the guest room block cut-off date is May 20, 2019. After that date OR when the room block fills, guestroom availability and rate will no longer be guaranteed.

BOOK NOW

Pricing and Registration Information:

	SAVE $200 Register & Pay by May 17, 2019	Register & Pay after May 17, 2019
ALL ACCESS PASS (Conference + Both Workshops)	$3395	$3595
Conference Only	$2195	$2395
Workshops:	$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.

Conference Code	669L19-NYC

Bringing a Team?	
3 - 4	10% Conference Discount
5 - 6	15% Conference Discount
7	20% Conference Discount
8 or more	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.

Terms and Conditions

Payment Policy

Payment must be received in full by the program date to ensure admittance. All discounts will be applied to the Program Only fee (excluding add-ons), cannot be combined with any other offer, and must be paid in full at time of order. Group discounts available to 3 or more individuals employed by the same organization, who register at the same time.

Delegate Substitutions and Cancellations

You must notify us by email at least 48 hrs. in advance of the conference if you wish to send a substitute participant. If you are unable to find a substitute, please notify us in writing no later than 10 days prior to the conference date and a credit voucher will be issued to you for the full amount paid, redeemable against any other ACI conference in the next 12 months. Delegates may not "share" a pass between multiple attendees without prior authorization.

All cancelled conference registrations will be subject to a cancellation fee of $350 and applicable taxes. Any product extensions (inclusive of workshops, receptions, masterclasses, etc.) will be subject to a cancellation fee of $50 and applicable taxes.

If you prefer, you may request a refund of fees paid less the applicable cancellation fee. No credits or refunds will be given for cancellations received within 10 days of the conference start date. No liability is assumed by American Conference Institute for changes in program date, content, speakers or venue. American Conference Institute reserves the right to cancel any conference it deems necessary and will, in such event, make a full refund of any registration fee, but will not be responsible for airfare, hotel or other costs incurred by registrants.

ACI's 7th Annual Legal, Regulatory and Compliance Forum on

DIETARY SUPPLEMENTS

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

June 18–19, 2019 | The InterContinental New York Times Square | New York, NY

American Conference Institute
45 West 25th Street, 11th Floor
New York, NY 10010

Attention Mailroom
If undeliverable to addressee, please forward to:
General Counsel; Dietary Supplements Counsel; Director, Dietary Supplements Regulatory

Update your Contact Information
If you would like us to change any of your details, please email **Data@AmericanConference.com**
And reference the conference code on the brochure.

REGISTRATION CODE

P10-669-CRN19

ACI American Conference Institute

In Collaboration with the

Council for Responsible Nutrition
The Science Behind the Supplements

EARN CLE CREDITS

ACI's 7th Annual Legal, Regulatory and Compliance Forum on

DIETARY SUPPLEMENTS

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

June 18–19, 2019
The InterContinental New York Times Square | New York, NY

2019 Program Highlights:

- An Interactive session on the **pros and cons of a mandatory product registry**
- A round table discussion on **new retailer-imposed testing and quality standards**
- Forecast for a **legal pathway for CBD** in food and dietary supplements
- A case study on **proprietary protections for NDIs**
- **International** focused sessions on the implications of **tariffs**, **trade wars**, and **Certificates of Free Sale**
- Spotlight on the **unique legal challenges** posed by **probiotics**
- Deep-dive analyses of **Direct-to-Consumer** and **Direct-to-Healthcare Provider** business models
- An assessment of **dietary supplement personalization**