ACI American Conference Institute

In Collaboration with the

Council for Responsible Nutrition
The Science Behind the Supplements

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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 City

Distinguished Faculty to Date:

CO-CHAIRS:

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

Steve Mister
President & CEO
Council for Responsible Nutrition

Jeff Brams
General Counsel, Vice President R&D and Regulatory
Garden of Life, LLC

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Senior Directory of Dietary Supplements and Tobacco Services
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Associate General Counsel, Regulatory Affairs & Privacy Officer
Nature's Bounty Co.

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Senior Vice President, Governance & Compliance
New Chapter, Inc. (A Procter & Gamble Subsidiary)

Paul E. Konney
Executive Vice President, General Counsel and Head of Global Regulatory Affairs
Metagenics, Inc.

Mark Levine
Associate General Counsel
RB Health

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President
American Herbal Products Association

Diana Morgan, MS
Head of Scientific & Regulatory Affairs
Care/of

Megan Olsen
Assistant General Counsel
Council for Responsible Nutrition

Randy Slikkers, MBA
Executive Director
Global Retailer and Manufacturer Alliance

This in-depth two day event will help you prepare for "one of the most significant modernizations of dietary supplement regulation and oversight in more than 25 years."

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**

POST-CONFERENCE WORKSHOPS: JUNE 20, 2019

A International Commercialization of Dietary Supplements

B Claims Substantiation Master Class

Media Partner: WholeFoods Magazine

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

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Business Information in a Global Context

Main Conference Day 1

Tuesday, June 18, 2018

7:00 | Registration & Continental Breakfast

8:15

Co-Chairs' Opening Remarks

8:30

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

In this session, Steve Mister will discuss both new and ongoing legal, regulatory, and compliance 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

- Examining FDA's position on a mandatory product registry
- Assessing the impact of CRN's OWL and whether voluntary product registration is effective vs. mandatory product registration

TABLETOP EXERCISE – NEW this year, an interactive session for audience engagement and knowledge sharing regarding the product registry debate

10:15 | Morning Coffee Break

10:30

U.S. Food and Drug Administration Keynote Address

Speaker, TBA

11:30

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

- Understanding the array of customs, international trade, and tariff laws associated with China
- Adjusting business models and plans in the wake of potential tariff increases, such as the challenges associated with new equipment purchases or cost of raw ingredients

12:15 | Networking Luncheon for Speakers and Attendees

1:15

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

- 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 and quality stand between retailers differ

2:15

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

- 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
- 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 Case Study: Coattails, Master Files, and NDIs

- 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

4:15

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

- 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

5:00 | Conference Adjourns to Day Two

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

> *"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*

Main Conference Day 2

Wednesday, June 19, 2019

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

- 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

9:30

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

- Examining new class action developments that affect the dietary supplement industry
- Interpreting recent Ninth Circuit court decisions involving the burden of proof for false labeling claims

10:30 | Morning Coffee Break

10:45

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

- Assessing what the FTC is looking for when studies are evaluated for claim substantiation
- Developing proper research methodologies to substantiate claims
- Interpreting recent FTC enforcement actions where the clinical study did not support the claim being made

11:30

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

- Adhering to the laws of the imported and exported country to ensure products are exported without any roadblocks
- 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 Exposure

- Exploring compliance models to ensure direct-to-consumer marketing is truthful and not misleading
- Identifying and addressing other key legal challenges associated with social media and e-commerce programs
- Analyzing the FTC's and FDA's policies and enforcement actions on direct-to-consumer marketing via social media outlets

2:00 CASE STUDY

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

In this session, our speakers will address the "ins and outs" of personalization of dietary supplements. They will help you 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

- Addressing the 2018 Prop 65 warning regulations and compliance challenges a year later
- Examining the recently amended California slack fill law – the most detailed in the nation – and its impact on the industry
- Adhering to California-specific requirements regarding disclosures and consumer consent for subscription-based programs
- Analyzing legislative proposals on single use plastics, packaging, fragrance disclosures, and hemp

3:45 CASE STUDY

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

- Determining the extent to which the medical community has embraced this model
- Studying the success of manufacturer models based solely on "direct to physician" business model

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

12:00 | Lunch for Speakers and Attendees for Post-Conference Workshops A & B

B 1:00 PM – 4:00 PM INTERACTIVE FORMAT

Claims Substantiation Master Class

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Pricing and Registration Information:

Registration Code	P10-669-CRN19

Conference Code	669L19-NYC

	Register & Pay by April 12, 2019	Register & Pay by May 10, 2019	Register & Pay after May 10, 2019
ALL ACCESS PASS (Conference + Both Workshops)	**$3295**	$3395	$3595
Conference Only	**$2095**	$2195	$2395
Workshops:		$600 (Each)	

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