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Council for Responsible Nutrition
The Science Behind the Supplements

American Conference Institute in collaboration with the Council for Responsible Nutrition presents:

EARN CLE CREDITS

ACI's 6th Annual
Legal, Regulatory and Compliance Forum on

Dietary Supplements

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

June 18–20, 2018 | InterContinental New York Times Square | New York, NY

Distinguished Faculty Confirmed to Date:

Co-Chairs:

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

Steve Mister
President & CEO
Council for Responsible Nutrition

Speakers:

FDA Keynote Address

Robert Durkin
Deputy Director, Office of Dietary Supplements Programs
CFSAN
U.S. Food and Drug Administration

Alyse M. Aruch
Corporate Counsel
Pfizer Consumer Healthcare

Kristen E. Blanchard
Vice President,
External Corporate Affairs
Nutramax Laboratories

Jeff Brams
GC and VP Int'l. Business & Science
Garden of Life

Christine Burdick-Bell
Vice President and General Counsel
Pharmavite LLC

Bill Carter
Chief Legal Officer
BodyBuilding.com

Tara Lin Couch, PhD
Senior Director, Dietary Supplements and Tobacco Services
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Kathleen Dunigan
Senior Staff Attorney
National Advertising Division
Advertising Self-Regulatory Council

Jeanette Fielding
Vice-President, Head Global Policy, Government and Stakeholder Affairs
Bayer HealthCare

Gregory W. Fortsch
Senior Legal Counsel – Regulatory/Privacy Officer
Nature's Bounty

David Hilton
Director of R&D
Natrol, LLC

Melissa Hung
Senior Corporate Counsel
The Clorox Company

J. Patricia Kim
General Counsel and Vice President of Regulatory Affairs
Swanson Health Products

Mark Levine
Associate General Counsel
RB

Lauren Medoff
Senior Counsel
AdvoCare International LP

Risa Schulman, PhD
President
Tap~Root

The dietary supplements industry faces a year of uncertainty and a time of transition in 2018. Stakeholders have more questions than answers concerning the latest legal and regulatory challenges facing the industry.

Attend this conference to gain clarity and obtain the latest information on:

- The shifting political and regulatory climate of the dietary supplement industry
- The current evolution of State AG enforcement actions
- New testing requirements for supplement manufacturers by retailers
- CBD hemp oil in the dietary supplements industry
- The new era of claims substantiation in the wake of *Prevagen*
- The future of fish oils in the wake of the *Amarin* ITC action
- Compliance controls for sophisticated cGMP standards

June 18, 2018: Workshop A
Class Action Litigation Boot Camp for Dietary Supplement Industry Stakeholders

June 20, 2018: Workshop B
Claims Substantiation Master Class

AMIN TALATI UPADHYE

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Monday, June 18, 2018
Pre-Conference Workshop A

2 pm – 5 pm | (Registration begins at 1 pm)

Class Action Litigation Boot Camp for Dietary Supplement Industry Stakeholders: A Guide for Designing Internal Preparedness Protocols, Timelines and Enlisting Outside Counsel

Main Conference Day One
Tuesday, June 19, 2018

7:00 | Registration & Continental Breakfast

8:00

Co-Chairs' Opening Remarks

8:15

The Shifting Political and Regulatory Climate of the Dietary Supplement Industry: Learning to Read the Barometer of the Hill and the Administration

- Predicting regulatory changes in this time of transition as new leadership positions are assumed within the FDA and FTC
- Assessing the impact of Dr. Gottlieb's first year at FDA on the dietary supplement industry
- Update on the future of DSHEA as the principal author – Senator Orrin Hatch – announced his retirement

9:00

FDA Keynote Address

Robert Durkin
Deputy Director, Office of Dietary Supplements Programs, CFSAN
U.S. Food and Drug Administration

9:45 | Morning Coffee Break

10:00

FDA Round Up: Update on FDA Guidances and Rulemaking Activity Impacting the Dietary Supplement Industry

- Exploring the concerns and questions related to the revised FDA draft NDI guidance
- Decoding the regulations involving new supplement facts and nutritional fact labels relative to reformulations, fiber, and added sugars
- Update on status of key terms in the dietary supplement space including "healthy", "natural", "organic", and "non GMO"

11:00

The Current Evolution of State AG Enforcement Actions and Related Repercussions for Manufacturer-Retailer Relations

- Update on recent AG activity in the supplement space
- Examining the nexus between new testing requirements for supplement manufacturers by certain retailers and the findings of state AG investigations
- Exploring the dietary supplement industry reaction to these new testing requirements

12:00 | Networking Luncheon

1:00

Update on Self-Regulatory Initiatives in the Dietary and Nutritional Supplement Space

With CRN's OWL now in its second year, we will get a first-hand glimpse of what the OWL and other self-policing platforms have accomplished and how they have evolved since their inception.

1:45

The Introduction of CBD Hemp Oil into the Dietary Supplement Space: Controversies, Concerns and Commerciality

- Understanding the use of CBD in hemp in the dietary supplement space
- Examining the medicinal aspect of hemp oil and understanding how CBD poses as an active constituent
- Determining whether hemp can be used legally in the dietary supplement space

2:15 | Afternoon Refreshment Break

2:30

The New Era of Claims Substantiation in the Wake of *Prevagen*

- Understanding the significance of the *Prevagen* case, *i.e., FTC et al. v. Quincy Bioscience Holding Co. Inc.* (S.D.N.Y. 2017) as the successor to Bayer for claim substantiation analysis for dietary supplements
- Exploring claims since Prevagen which were the recent subject of FTC scrutiny for lack of proper scientific support
- Survey of recent state AG consumer protection and NAD activity relative to claim substantiation

3:15

The Impact of Social Media Influencers and Paid Promoters on the Advertising and Promotion of Dietary Supplement Products

- Creating an effective strategy of marketing and advertising in the dietary and nutritional space using social media, the internet, YouTube channels, and other avenues
- Exploring the impact of FTC warning letters on influencers and paid promoters in the dietary supplement space
- Understanding the relationship between the supplement company and influencers/promoters who advertise products but donot mention they are paid to do so

4:00

Case Study on the Future of Fish Oils: Exploring the Consequences of Retroactively Declaring a Dietary Supplement a Drug

- An analysis of the Amarin *Vascepa* case and the novel use of an ITC petition
- Understanding the wider significance of the Amarin case to the fish oil supplement industry
- Exploring the ramifications of Amarin's attempt at the ITC to other dietary supplement products

4:45

Implementing Compliance Controls to Meet New Sophisticated cGMP Standards

- Understanding the FDA's more sophisticated approach to dietary supplement cGMPs
- Petitioning the FDA for an exemption to the 100% identity requirement for ingredient testing
- Assessing the impact of program alignment under Dr. Gottlieb

5:30 | Conference Adjourns to Day Two

CRN Members Discount

Registration Code	P10-669-CRN18
Conference Code	669L18-NYC

FEE PER DELEGATE	Register & Pay by April 13, 2018	Register & Pay by May 18, 2018	Register & Pay after May 18, 2018
☐ Conference Only	$1995	$2095	$2295
☐ Conference & Workshop A or B	$2595	$2695	$2895
☐ All Access Pass: Conference & Both Workshops	$3195	$3295	$3495

Main Conference Day Two
Wednesday, June 20, 2018

7:30 | Continental Breakfast

8:00

Co-Chairs' Opening Remarks and Recap of Day 1

8:15

Unraveling the Complexities of the Next Wave of FSMA Regulations

- Understanding the latest FDA Rule amendments to FSMA and their impact the dietary supplement industry
- Determining parts of FSMA relevant to contract management including exemptions Ensuring compliance with FSVP

9:00

Coattail Claims: The Latest Influx of Class Action Litigation Impacting the Dietary Supplement Space

- Examining recent class action filings against dietary supplement manufacturers
- Devising strategies to minimize class action exposure and mitigate liability
- Exploring the link between FTC, NAD, state AG and federal enforcement activity and the plaintiffs' bar

10:00 | Morning Coffee Break

10:15

Unique Prop 65 Challenges for the Dietary Supplement Industry: Update on the Latest" Chemicals" Found to Cause Harm

- Reviewing the new warning regulations and how they impact dietary supplements
- Updates on affirmative litigation regarding the First Amendment and Labor Code listing process
- Responding to retailer inquiries

11:00

Understanding International Dietary Supplement Commercialization in the Current Geo-Political Atmosphere

- Appreciating how the future of NAFTA and the reality of Brexit and other Populist movements may affect the U.S. Supplement industry's trade ability
- Deciphering distinctions between registration, pre-market approval, and post-surveillance review in foreign jurisdictions and understanding how they may be affected by the current political climate
- Highlighting aspects of post-surveillance that is unique to Asia and Europe
- Exploring how U.S. – Asia trade relations may influence supplement manufacturing in the U.S.

11:45

Exploring the Risks of the Direct to Physician Supplement Sales Model

- Understanding the promotion of supplements to healthcare practitioners
- Analyzing regulations of drugs marketed to healthcare practitioners and how these may be utilized in the supplement space considering the lack of regulation in this space
- Performing a risk analysis when selling supplements to healthcare practitioners

12:30 | Conference Ends

Wednesday, June 20, 2018
Post Conference Workshop B

2 pm – 5 pm (Registration begins at 1 pm)

Claims Substantiation Master Class

(Luncheon is available for Workshop Attendees beginning at 12:30 pm)

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