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Agenda at a Glance

7:45
Registration & Breakfast

8:00
Icebreaker

8:45
Chairperson's Opening Remarks
Jeff Golini
Executive Scientist
All American Pharmaceutical

9:00
Beauty from Within – Examining the Regulatory Concerns for Ingestible Skin, Hair, and Nail Boosting Supplements

Since ancient times, beauty and youthfulness have been linked, and vanity is not reserved for individuals of any age or gender. More and more people are concerned about such things as greying or thinning hair, wrinkles and sagging skin and brittle nails; so, the thought that these things can be restored to their "former glory" simply by taking a daily dietary supplement or sipping a "beauty beverage" is appealing to many. All of which explains why so many cosmetics and supplement companies are tailoring products to meet this growing consumer market. This session will take a look at the regulatory and compliance issues that arise when providing a product that claims to improve beauty from the inside out.

Speakers:
Diana Morgan
Head of Scientific & Regulatory Affairs
Care/Of

Stan Soper
VP, International & Chief Legal Officer
Nutraceutical Corporation

9:45
Improved Labeling Compliance: Strategies for Identifying, Avoiding and Resolving Labeling Mistakes

Labeling has never been stricter nor have consumers ever been so knowledgeable about ingredients. This means companies need to be more aware of how their products are marketed to ensure compliance. This interactive panel will review best practices as to how cosmetics, personal care and supplement companies can ensure compliance in their labeling practices.

We will:
- Examine new regulations and strategies to avoid and resolve labeling mistakes
- Understand how to implement mandatory labeling changes effectively and quickly to correct labeling errors
- Determine how marketing can help during the labeling process

Speaker:
Jeff Brams
General Counsel & VP R&D and Regulatory
Garden of Life

11:30
Lacey Act Compliance and Supply Chain Transparency – Do you have a Compliance Program?

The Lacey Act is the oldest wildlife protection statute in the United States. It was originally enacted in 1900 to protect animal species. In 1981, Congress expanded the Lacey Act to cover certain plants and plant parts taken in violation of US domestic law, but not foreign law. In 2008, Congress substantially expanded coverage of the Lacey Act to include all types of plant (including lumber, wood and other plant products – including essential oils and other natural products) and animal materials..

The 2008 Amendment was the first ban on wood and plant products that sought to target illegal harvest outside the United States, and to provide better transparency into the source and species of plant and wood products being imported into the United States. This session will discuss how this US statute affects industries utilizing plant ingredients/constituents in finished products and the push for supply chain transparency.

Key points include:
- Background on the Lacey Act and prohibitions
- Application to natural products industry and due care standards
- Looking ahead and approaches to developing a quality compliance program

Speaker:
Jessica Harris
International Trade Compliance
Young Living

> "If you think the pursuit of good health is expensive and time consuming, try illness."
>
> - **Lee Swanson,**
> *Founder & Consultant*
> *Swanson Health Products*

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10:45
Networking Break

11:05
Understanding Claims Substantiation and How Social Media Influencers & Claims Can Impact You

In today's digital world, companies have even more marketing and advertising platforms than ever before; and social media outlets have given rise to influencers, paid promoters and celebrities using their voice to speak out on many products. In addition, companies that utilize distributor networks to market and sell their products have a larger reach than ever before through the use of social media. These individuals tend to have a lot of weight to consumers who rely on product assessments and reviews before making a purchase. In this session we will examine how to utilize these influencers and paid promoters while following the FTC regulatory guidelines.

We will discuss topics such as:

- What types of claims should we be aware of – soft, hard, marketing, fluff, direct, implied
- Understanding implied claims through social media, testimonials and influencers
- Develop ways to prevent or counteract trolls, fake review by competitors or other adverse and negative marketing
- Examine the FTC guidelines on influencer marketing on social media including the use of hashtags
- Understand the impact of FTC warning letters for distributors, influencers and paid promoters in social media
- Determine who is responsible for claims and determining which claims could and should be substantiated
- Create a policy for distributors and influencers/promoters to eliminate the potential for problems
- Examine regulatory and compliance liability concerns as they apply to social media
- Learn how to utilize technology to monitor your company's/brand's name across social media platforms

Spakers:
Alyse Aruch
Senior Corporate Counsel
Consumer Healthcare
Pfizer

Neshat Davoodi Soofi
Head of Product Safety
Quality & Integrity
Brandless

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

11:50
Interactive Breakout Discussions

1- Examine High Impact Tools for Cosmetics Companies to Advance Regulatory Harmonization
2- 25 Years and Counting Revisiting DSHEA
3- Examining New Sunscreen Rules
4- Interpreting the USDA National Bioengineered Food Disclosure Law

12:35
Lunch

1:40 pm
Cosmetics Breakout Session

Exploring Cosmetics' Chemical Concerns
Some ingredients in cosmetics and personal care products are chemicals that can be hazardous to consumers' health. Many organizations such as the EWG, European Commission, EU REACH, the EU Cosmetics Regulation, CIR, TSCA, Green Chemistry, International Fragrance Association, are evaluators of cosmetic products, but there are many, many more that need to be navigated. Cosmetic companies can save millions of dollars, if they are able to identify what chemicals or ingredients might create issues for them before using them.

In this session, we will:

- Examine various chemical concerns being faced by the cosmetics and personal care products industry
- Discuss product contamination or concerns
- Determine how companies are doing multiple product testing to ensure products meet standards
- Identify various international regulations and how they may affect your brand – ie. animal testing with chemicals
- Explore alternative ingredients can be used to banned products or to avoid problems
- Identify what ingredients consumers are (or are not) looking for in their products

1:40
Cosmetics Breakout Session
Supplements Breakout Session

There have been many cases of adulterated supplements containing pharmaceuticals and products that may be harmful to consumers. Frequently adulterated supplements include those focused on weight loss, bodybuilding sexual enhancement amongst others. Manufacturers and brands within the supplement industry need to do all that they can to reduce the risk and problems that come with product adulteration. In this session we will discuss tips and practices to avoid product adulteration.

Speaker:
Jeff Golini
Executive Scientist
All American Pharmaceutical

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Agenda at a Glance

02:15
The Farm Bill Has Been Passed: How will Federal Refinement of Rules & Regulations for CBD and Hemp Oil Affect the Cosmetics, Personal Care Products and Dietary Supplements

A lot of consumers are starting to view CBD more like a vitamin, because it has been said to contain many vitamins and fatty acids and even possess anti-inflammation properties. And many cosmetics companies are exploring how to include CBD in their products. However, it is still a relatively new, unexplored and undocumented product / ingredient; in addition, there is so much uncertainty as to how it can and will be regulated.

In this session, we will:

- Reviewing the impact of the Farm Bill on hemp products that contain CBD's
- Interpreting the FDA laws and regulations that govern cosmetics and applying them to hemp and CBD products, in light of the pronouncements of the FDA Commissioner following passage of the Farm Bill
- Understand the current risk hierarchy of CBD and Hemp Oil
- Examine how states are navigating compliance as it relates to the massively scaling CBD industry
- Explore why many cosmetic companies are and should be interested in the use of CBD in their products
- Examine current case law related to the manufacturing and distribution of CBD
- Determine if it is possible for CBD products to truly be free of THC

Speaker:
Ronie Schmelz
Counsel
Tucker Ellis

03:00
Assessing Clean, Green, Natural and non-GMO: Examining the Regulatory Soundness and Potential Liabilities for the Beauty & Supplements Industry

As the market continues to evolve, buzz words like "clean", "green", "natural", "non-GMO", "vegan", "anti-cruelty" become that much more important to beauty and supplement brands and manufacturers to meet consumers demands for a healthy life-style. However, this has caused cosmetics, supplement and functional food companies a variety of headaches as they try to under-stand and navigate the new challenges that using these terms create.

In this session, we will look into such things as:

- Understanding what the implications and risks associated with labeling supplements, cosmetics and personal care products as "natural"
- Examining the status of the new labeling requirements, and assessing whether your company is ready for the compliance deadlines
- Understanding new regulations requiring labeling for bioengineered products
- 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
- Assessing the challenges with labeling products as preservative-free and natural or vegan, gluten free, peanut free, etc.
- Deciphering the current standard for USDA requirement for "organic" and how does this apply to cosmetics and supplements?
- Lessons learned from FDA requirements for natural versus synthetic flavors and how the cosmetics & supplements industries adapt to these standards

Speaker:
Kristi Wolff
Partner
Kelley Drye & Warren LLP

3:30
Networking Break

3:45
Utilizing Technology to Modernize Your Regulatory & Compliance Playbook

In the evolving regulatory landscape, it is critically important for organizations to respond to new regulations with agility. Compliance technology can help alleviate this pressure by extracting the maximum value from data, aiding decision-making, monitoring the market and easing your compliance burdens.

We will look at things such as:

- Web-crawlers
- AI and machine learning
- Q&A technologies
- Text analytics
- And more

> "When the farm bill passed last year, we were beyond thrilled. This ended a multi-decade prohibition on hemp. We really need the FDA to join in and help us lay a path toward a regulated legal product"
>
> **- Jonathan Miller,**
> *General Counsel, U.S. Hemp*

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Agenda at a Glance

04:05
Crisis Management: You've Received a Warning Letter, Now What?

A warning letter from the FDA or FTC is basically an instruction cease & desist whatever conduct they think is necessary until you can show compliance with regulations. Common reasons for warnings are misbranding, mislabeling, non compliance with quality manufacturing procedures, product adulteration, and more. This session, willwalk through what can and should be done upon receipt of a warning letter.

We will look at things such as:

- Understanding the various reasons for a warning letter
- Determining the thin line between compliance and noncompliance
- Discussing the need for an FDA/FTC lawyer
- Examining practical solutions that help you comply respond to the warning and continue in business
- Communicating changes to customers to not only stay in compliance but to repair or retain brand reputation

Moderator:
Varsha Nainani
Corporate Vice President Quality & Regulatory | Dhaliwal Laboratories

04:30
The World is at Your Fingertips: Determine Which National and Global Markets are Best & Easiest to Enter and Methods to Ensure Compliance in Marketing to these Markets

This interactive panel discussion will share insight from leaders in the dietary supplements and cosmetics industries as to which markets are currently on the leader - board for product expansion. As we look at markets such as Canada, Japan, Korea, Brazil, China, and across the Americas and more, we will try to determine why these markets make sense, potential obstacles to be faced in each market and manners to secure marketing compliance in each market.

Examining the Rules and Regulations to Import DIN/NPN Products in to Canada
The basic but important things to consider when you want to sell any cosmetic prod- ucts into Canada.

Moderator:
Martine Bertrand
Customs Compliance Manager | Sephora

05:15
Chairperson's Closing Remarks

Moderator:
Jeff Golini
Executive Scientist
All American Pharmaceutical

05:30
Cocktail Reception

> "I'm concerned that changes in the supplement market may have outpaced the evolution of our own policies and our capacity to manage emerging risks. To continue to fulfill our public health obligations we need to modernize and strengthen our overall approach to these products."
>
> - **Scott Gottlieb**,
> *Former Commissioner, Food & Drug Administration (FDA)*