DIETARY SUPPLEMENTS: REGULATORY STRATEGY

NOVEMBER 13-14, 2017 | ARLINGTON, VA

Fostering the Growth & Development of the Dietary Supplement Industry through Robust Regulatory Compliance, from Label Claim Substantiation to Adherence with Evolving FSMA Regulations, to Ensure Safe & Effective Supplements for Consumers

CONFERENCE SPONSORS:

SILVER:

BENJAMIN L. ENGLAND & ASSOCIATES

Kelley Drye

NUTRAVIGILANCE™ Supplement Safety Solutions VERIFIED

BRONZE:

Hyman, Phelps & McNamara PC
www.hpm.com www.fdalawblog.net

esha RESEARCH
Genesis R&D®

TABLE-TOP:

DECERNIS

DOCUMENTATION:

EAS CONSULTING GROUP

TAP ROOT
TAPPING YOUR DEEPEST RESOURCES

Q1 PRODUCTIONS
DEDICATED TO QUALITY FIRST™

DIETARY SUPPLEMENTS: REGULATORY STRATEGY

NOVEMBER 13-14, 2017 | ARLINGTON, VA

PROGRAM PRESENTERS:

REGULATORY & GOVERNMENT AUTHORITIES

Richard Cleland
Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices
FEDERAL TRADE COMMISSION (FTC)

Paul M. Coates, Ph.D.
Director, Office of Dietary Supplements
NATIONAL INSTITUTES OF HEALTH

Carolyn L. Hann
Senior Attorney, Bureau of Consumer Protection, Division of Advertising Practices
FEDERAL TRADE COMMISSION (FTC)

Phillip Ziperman
Director, Office of Consumer Protection
ATTORNEY GENERAL FOR THE DISTRICT OF COLUMBIA

Cara Welch
Senior Advisor, Office of Dietary Supplement Programs
CFSAN/FDA

DIETARY SUPPLEMENT INDUSTRY LEADERS

Salma Fathalla
Director of Quality Assurance
NUTRITION 21

Hame Persaud
Executive Vice President
HP INGREDIENTS

Florence Okaro
Vice President Regulatory Operations
NATURE'S BOUNTY

Mike DiMaggio
Chief Legal Officer
NUTRABOLT

Alan Lewis
Director of Special Projects
NATURAL GROCERS

Ross Peterson, Ph.D.
Sr. Regulatory Affairs Specialist
ABBOTT NUTRITION

Talash Anne Likimani
Senior Director, Regulatory Affairs
ARBONNE INTERNATIONAL

Pawel Rudzinski
Vice President of Quality
THE NATURE'S BOUNTY CO.

Russell Michelson
Senior Manager, Worldwide Safety and Regulatory
PFIZER CONSUMER HEALTHCARE

Paul Konney
EVP, General Counsel & Head of Global Regulatory Affairs
METAGENICS

Dr. Carl Hastings
Vice Chairman and Chief Scientific Officer
RELIV INTERNATIONAL

SUPPLEMENT ASSOCIATION LEADERSHIP

Daniel Fabricant, Ph.D.
Executive Director, CEO
NATURAL PRODUCTS ASSOCIATION

P. Courtney Gaine, PhD, RD
President and CEO
THE SUGAR ASSOCIATION, INC

Corey Hilmas
SVP of Scientific & Regulatory Affairs
NATURAL PRODUCTS ASSOCIATION

Karen Howard
CEO and Executive Director
ORGANIC AND NATURAL HEALTH ASSOCIATION

LEGAL EXPERTS & INDUSTRY CONSULTANTS

Michele Corash
Senior Partner
MORRISON FOERSTER

Craig M. Spierer
Partner
HARRIS BEACH, PLLC

A. Wes Siegner, Jr.
Director
HYMAN, PHELPS & MCNAMARA, P.C.

Rick Collins, Esq.
Partner
COLLINS GANN MCCLOSKEY & BARRY PLLC

Ivan Wasserman
Partner
ALMIN TALATI UPADHYE

Benjamin England
Owner
BENJAMIN L. ENGLAND & ASSOCIATES

Maya Wilson
Regulatory Compliance Specialist
ESHA RESEARCH

Stephen Schmitz
Co-Founder & Principal
SUPPLEMENT SAFETY SOLUTIONS

DIETARY SUPPLEMENTS: REGULATORY STRATEGY

DAY ONE | MONDAY, NOVEMBER 13

8:00 REGISTRATION & WELCOME COFFEE

8:40 CHAIRPERSONS OPENING REMARKS

8:45 KEYNOTE ASSOCIATION LEADERSHIP PANEL: FUTURE OF DIETARY SUPPLEMENT REGULATION

As an industry rooted in self-regulation, the dietary supplement business has fostered the establishment and growth of a large number of well-respected professional associations, who provide regulatory and industry thought leadership for executives and corporations throughout the industry. The shift in the political landscape has caused uncertainty concerning the regulatory outlook for dietary supplements, as well as current changes to ingredient and nutrient labelling, specific state regulatory involvement and NDI reform. Executives from various industry associations will provide perspectives and analysis of the current regulatory environment, new administration and FDA commissioner, and how the new political landscape will affect the dietary supplement industry and future regulations.

MODERATOR:

Benjamin England, *Owner*
BENJAMIN L. ENGLAND & ASSOCIATES

PANELISTS:

Paul M. Coates, PH.D., *Director, Office of Dietary Supplements*
NATIONAL INSTITUTES OF HEALTH

Daniel Fabricant, Ph.D., *Executive Director, CEO*
NATURAL PRODUCTS ASSOCIATION

Karen Howard, *CEO and Executive Director*
ORGANIC AND NATURAL HEALTH ASSOCIATION

P. Courtney Gaine, PhD, RD, *President and CEO*
THE SUGAR ASSOCIATION, INC

9:45 INDUSTRY ASSOCIATION BREAKOUT DISCUSSIONS

With a high number of well-respected and renowned associations supporting and providing a voice for the dietary supplement industry, there is much to be gained from small group discussions with association leadership, who maintain a close eye on the pulse of regulatory and legislative change, relaying this information back to members. Following the keynote panel discussion, participants will have an opportunity for direct dialogue and discussion with the most relevant association, to collaborate and exchange views on specific segments of the dietary supplement industry.

BREAKOUT DISCUSSION GROUP LEADERS:

Paul M. Coates, PH.D., *Director, Office of Dietary Supplements*
NATIONAL INSTITUTES OF HEALTH

Daniel Fabricant, Ph.D., *Executive Director, CEO*
NATURAL PRODUCTS ASSOCIATION

Karen Howard, *CEO and Executive Director*
ORGANIC AND NATURAL HEALTH ASSOCIATION

P. Courtney Gaine, PhD, RD, *President and CEO*
THE SUGAR ASSOCIATION, INC.

10:15 COFFEE & NETWORKING BREAK

REGULATION OF NEW DIETARY INGREDIENTS: FDA, LEGAL & CORPORATE PERSPECTIVES

Released in August of 2016, the FDA document Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry, replaced the 2011 document, providing industry executives with an updated framework for regulatory submissions, safety goals of the agency, as well as criteria for determining the need for the submission. The document also provides information for industry on the evidentiary support and chemistry information that should be included with the submission based on the various categorizations of potential ingredients.

10:45 MODULE 1: FDA UPDATES ON NEW DIETARY INGREDIENT SUBMISSIONS

- Qualified safety studies to demonstrate safety
- Refinement of dietary ingredient safety standards
- Updated guidance documents available for industry
- Ongoing collaborative efforts with the Agency

Cara Welch, *Senior Advisor, Office of Dietary Supplement Programs*
CFSAN/FDA

11:15 MODULE 2: LEGAL RAMIFICATIONS OF ADHERENCE WITH NDI APPLICATIONS

- Legal framework surrounding NDI submission process
- Managing the risk & financial impact of NDI applications
- Analysis and interpretation of recent guidance documents

Mike DiMaggio, *Chief Legal Officer,* **NUTRABOLT**

Craig M. Spierer, *Partner, Harris Beach,* **PLLC**

11:45 MODULE 3: INDUSTRY, LEGAL & REGULATORY PANEL DISCUSSION

- Assessing the need for an NDI submission
- Industry experiences in the NDI pathway
- Case study examples highlighting success

Cara Welch, *Sr Advisor, Office of Dietary Supplement Programs*, **CFSAN/FDA**

Mike DiMaggio, *Chief Legal Officer,* **NUTRABOLT**

Craig M. Spierer, *Partner,* **HARRIS BEACH, PLLC**

A. Wes Siegner, *Jr. Director,* **HYMAN, PHELPS & MCNAMARA, P.C.**

12:15 LUNCHEON FOR ALL CONFERENCE GUESTS

1:15 KELLEY DRYE PRESENTATION

2:00 PANEL: STATE-LEVEL REGULATION OF DIETARY SUPPLEMENTS

State Attorney Generals exercise legal authority and oversight of dietary supplements to ensure supplement companies are adhering to FDA regulations that protect consumer's health and safety, and hold the industry accountable for fraudulent activities. These actions at the state level have been in response to challenges with the FDA regarding lengthy response timelines, a lack of resources, and changes in executive leadership. Attorney Generals are providing a new dynamic that supplement companies must be aware of, as participation at a state level may increase substantially moving forward.

- Use of "Unfair and Deceptive Acts and Practices" statutes
- New York as a trailblazer in state level regulatory involvement
- Industry collaboration with state and federal agencies

Rick Collins, Esq., COLLINS GANN MCCLOSKEY & BARRY PLLC

Alan Lewis, NATURAL GROCERS

Philip Ziperman, ATTORNEY GENERAL FOR THE DISTRICT OF COLUMBIA

Dr. Carl Hastings, RELIV INTERNATIONAL

2:45 NEW YORK ASSEMBLY BILL 7607: DIETARY SUPPLEMENT IMPACT ASSESSMENT

- Overview of 7607 provisions including:
  - Inclusion of new disclosure statements
  - Labeling including all supply chain partners
- Potential impact on dietary supplement industry
- Understanding the motives behind the regulation

Rick Collins, Esq., *Partner,* **COLLINS GANN MCCLOSKEY & BARRY PLLC**

3:30 COFFEE & NETWORKING BREAK

4:00 PROP 65: DIETARY SUPPLEMENT TOXIN CLARIFICATION

- Synopsis of listed chemicals and toxicity levels
- Updates to "clear and reasonable" safe harbor warnings
- Increasing debate around pesticides ingredients
- Modifications in testing requirements for prop 65

Michele Corash, *Senior Partner,* **MORRISON FOERSTER**

4:45 PROACTIVE EFFORTS ON GMO LABELLING FOR THE DIETARY SUPPLEMENT INDUSTRY

The dietary supplement industry is guided by oversight from the U.S. Department of Agriculture on a wide range of products including those incorporating herbs, vitamins, minerals and ergogenic acids, as well as oversight of claims such as natural, and GMO related statements. Of particular interest to dietary supplement manufacturers are ongoing changes to nutrition facts panels, as well as guidance surrounding GMO. Providing a perspective on current regulatory initiatives and the industry at large, participants will gain knowledge and forward thinking approaches for continued compliance, and new regulatory standards for GMO labelling.

- Recent USDA updates related to supplement labels
- Nutrition facts panel related to protein calculations
- Regulation surrounding GMO & engineered items
- Utilization of appropriate "Natural" claims

Karen Howard, *CEO and Executive Director*
ORGANIC AND NATURAL HEALTH ASSOCIATION

Alan Lewis, *Director of Special Projects,* **NATURAL GROCERS**

5:30 CONCLUSION OF DAY ONE PRESENTATIONS

DIETARY SUPPLEMENTS: REGULATORY STRATEGY

DAY TWO | TUESDAY, NOVEMBER 14

8:15 CHAIRPERSONS OPENING REMARKS

8:30 COMPREHENSIVE NUTRAVIGILANCE: ASSURING THE SAFETY OF YOUR PRODUCTS WHILE BUILDING BRAND EQUITY (ADD TO AGENDA)

Dietary supplement and nutraceutical companies are required by DSHEA and Title 21 CFR 111 to assure the safety of their products in a pre-market setting. Consumer inquiry, adverse event collection and serious adverse event reporting is a critical aspect of that requirement via post-market surveillance under the Dietary Supplement and Nonprescription Drug Consumer Protection Act. The Nutravigilance® best-practices approach keeps the company at the center of all customer interactions to optimize not only safety signal detection, future product development and continuous manufacturing quality improvement, but also utilize this valuable feedback as another consumer touch point for brand equity. This interactive seminar will focus on the importance of having a robust nutravigilance system, and will discuss the tools, standard operating procedures, employee training, and leadership mindset required to meet or exceed current regulatory requirements in a cost-effective manner, and be prepared for an FDA inspection.

TRACK ONE - CLAIMS REGULATION

9:15 FTC PERSPECTIVE: HOT TOPICS & ENFORCEMENT TRENDS FOR DIETARY SUPPLEMENTS

Companies producing dietary supplements must adhere to various FDA guidelines in order to take products to market, and while the FDA provides a level of promotional guidance, the Federal Trade Commission (FTC) is the federal agency responsible for ensuring that advertising claims about dietary supplements and other products are truthful, substantiated, and not misleading. A review of recent FTC law enforcement actions will highlight legal issues to consider when marketing such products. In order to strike a balance between marketing goals and regulatory requirements, dietary supplement marketing executives must consider potential responses from the FTC. A frank discussion led by the agency will provide a framework for understanding recent actions and enforcement trends.

- FTC authority over dietary supplement marketing and overlap with FDA
- Overview of FTC claims substantiation requirements
- Hot topics including cognitive, pain relief, disease treatment, & weight loss claims
- How food and dietary supplement marketers can ensure that their substantiation matches their claims
- Recent FTC cases of interest to dietary supplement marketers

Carolyn Hann, *Senior Attorney, Bureau of Consumer Protection, Division of Advertising Practices*
FEDERAL TRADE COMMISSION

10:00 LESSONS LEARNED POST-BAYER: SUPPLEMENT CLAIM SUBSTANTIATION

As dietary supplement manufacturers continue to make claims regarding the health benefits of products, the recent Bayer case has provided a framework of good practices followed and is being lauded by industry as a victory for dietary supplement manufacturers across the country. While the US government continues to focus increasing efforts on ensuring supplement claims do not mislead consumers, manufacturers are not responsible for gold standard clinical research to support products when making implied, structure/function claims. Taking a collaborative approach as Bayer has in label development and claim substantiation, as well as full and comprehensive documentation with supporting medical research ensured that claims were fully backed up with robust data.

- Differentiating structure/function vs. disease claims
- Defining expressed vs. implied claims for supplements
- Establishing best practices for label claims post-Bayer

Richard Cleland, *Assistant Director, Bureau of Consumer Protection, Division of Advertising Practices*
FEDERAL TRADE COMMISSION (FTC)

Ivan Wasserman, *Partner*
AMIN TALATI UPADHYDE

10:45 COFFEE & NETWORKING BREAK

11:15 PANEL: CRAFTING ACCURATE AND SUBSTANTIATED CLAIMS FOR DIETARY SUPPLEMENT LABELS

- Comparing egregious vs legitimate claims
- Health & disease claims: limiting inclusion
- Identification of claims that are effective & accurate

Corey Hilmas, NATURAL PRODUCTS ASSOCIATION
Florence Okaro, NATURE'S BOUNTY
Ross Peterson, Ph.D., ABBOTT NUTRITION
Talash Anne Likimani, ARBONNE INTERNATIONAL
Maya Wilson, ESHA RESEARCH

TRACK TWO - QUALITY & MANUFACTURING REGULATION

9:15 SITE INSPECTIONS & AUDITS: DIETARY SUPPLEMENT INDUSTRY EXPERIENCES & TREND ANALYSIS

As the FDA increases the number and frequency of audits within the dietary supplement industry, manufacturers must consider appropriate preparations for both scheduled as well as unannounced audits to ensure documents and facilities are appropriately presented. Recent warning letters indicate inspection trends focused on specification testing as well as substantiation of expiration dates, as well as concerns surrounding formulation testing and labeling documentation. Learning from recent audit experiences and sharing lessons learned will provide the audience with an opportunity for frank dialogue on the preparations that must be made in order to maintain compliance.

- Formulation data integrity & record keeping methods
- Scientific methods being used by FDA to substantiate:
  - Expiration dates
  - Formulation
  - Non-adulteration
- Lessons learned and proactive measures taken to comply

Salma Fathalla, *Director of Quality Assurance*
NUTRITION 21

10:00 DIETARY SUPPLEMENT MANUFACTURER OVERSIGHT OF DISTRIBUTOR & CONTRACT MANUFACTURER GMP

In order to leverage cost-savings, many dietary supplement manufacturers and brands partner with distributors and contract manufacturers to develop and produce high quality products while reducing overall product costs, though these relationships cause an additional layer of both risk and monitoring which must be conducted to ensure products remain unadulterated. Recognizing areas of required oversight of contract manufacturers in maintaining alignment with GMP standards and distributor oversight of GMP activities is an essential component in a risk-adverse approach to manufacturing. As claims of adulteration and FDA inspection activity continues to increase, appropriate oversight and monitoring to ensure GMP alignment is of critical importance.

- Defining responsibilities of manufacturers & distributors
- Ensuring product specifications are being consistently met
- Batch record management at contract facilities
- Adulteration concerns surrounding GMP compliance

Hame Persaud, *Executive Vice President*
HP INGREDIENTS

10:45 COFFEE & NETWORKING BREAK

11:15 ANALYSIS OF FDA FSMA REGULATION ON DIETARY INGREDIENTS & DIETARY SUPPLEMENT MANUFACTURERS

- Analysis of FSMA application on dietary supplement industry
- Overview and explanations critical sub-sections of the Act:
  - 21 CFR 111: cGMP for Dietary Supplements
  - 21 CFR 117: cGMP, Hazard Analysis for Human Food
- Interpreting regulatory aspects and subpart exemptions
- Proactive industry preparedness for compliance

Pawel Rudzinski, *Vice President of Quality*
THE NATURE'S BOUNTY CO.

DAY TWO CONTINUED...

DIETARY SUPPLEMENTS: REGULATORY STRATEGY

DAY TWO | TUESDAY, NOVEMBER 14

12:00 MULTI-JURISDICTIONAL FEDERAL ENFORCEMENT IN DIETARY SUPPLEMENT AND INGREDIENT IMPORTS

New ingredients and finished products imported into the U.S are regulated across multiple federal government agencies, which have new access to comprehensive commercial and regulatory data used to enforce dietary supplement requirements before, during and after importation. Though many emerging enforcement actions originate at the border by Customs, FDA or USDA, these and other agencies are now using enhanced Customs data sets to initiate investigations of potential violations post importation. Customs and Partner Government Agencies are increasing their demands for specific information to justify classifications, valuations, origin (for free trade agreement reduced duty treatment) and product labeling claims. An analysis of specific case studies will feature the new and increasing use of integrated federal enforcement of regulatory and trade obligations to highlight the necessary international trade awareness required by the dietary supplement industry.

- Integration of FDA & Customs import enforcement tools
- Increased incidents of "pilling on" by USFW & USDA:
  - USFW CITES enforcement efforts
  - USDA NOP enforcement actions
- Customs investigations into:
  - Origin
  - Classification
  - Valuation
- Enhanced investigations of existing import & trade

Benjamin England, *Owner*
BENJAMIN L. ENGLAND & ASSOCIATES

12:45 LUNCHEON FOR ALL CONFERENCE GUESTS

1:45 DIETARY SUPPLEMENT FACTS PANEL: UPDATES & FUTURE REGULATORY GUIDANCE

Following the overhaul of the FDA's iconic Nutrition Facts label, subsequent modifications to the Supplement Label have been introduced, to align label formats and values to increase consumer readability and create a unified format for information. Supplement manufacturers face a wide range of challenges in compliance, from interpreting regulation and associated exemptions, to ensuring dietary values are re-calculated in-line with new requirements. With uncertainty regarding deadlines but with a certainty that changes will need to be made, supplement manufacturers are preparing now for potentially expensive label modifications in the future.

- Redefining product values in-line with new panel guidelines:
  - Fibers | Sugars | Minerals
- Integration of ingredient additions on product labels
- Ensuring compliance with revised timelines & deadlines
- Use of the Online Wellness Library as a research tool

Florence Okaro, *Vice President Regulatory Operations*
NATURE'S BOUNTY

Ross Peterson, Ph.D., *Sr. Regulatory Affairs Specialist*
ABBOTT NUTRITION

2:30 PANEL: GLOBAL REGULATION OF DIETARY SUPPLEMENTS: ENSURING COMPLIANCE & SUPPORTING COMMERCIALIZATION

As dietary supplement manufacturers continue to expand business and product offerings into markets outside of the United States, regulatory affairs executives must expand knowledge and skill-sets in order to effectively guide products into new markets, meeting regulatory compliance guidelines that may differ widely from FDA standards. Global formulations may also differ based on specification ranges unique to individual country guidance documents and must be considered prior to market entry. Comparing the regulatory guidelines in varied global markets against current US FDA standards will provide participants with an eye towards future market trends and the regulatory responsibilities required.

- International label claims & substantiation
- Formulary development & specification
- Variables in manufacturing documentation

Russell Michelson, *Senior Manager, Worldwide Safety and Regulatory*
PFIZER CONSUMER HEALTHCARE

Talash Anne Likimani, *Senior Director, Regulatory Affairs*
ARBONNE INTERNATIONAL

Paul Konney, *EVP, General Counsel & Head of Global Regulatory Affairs*
METAGENICS

3:15 CLOSING REMARKS & PROGRAM CONCLUSION

ATTENDEE PROFILE:

Executives that will find this program of greatest relevance are those currently working to maintain the compliance, regulatory and ethical considerations of dietary supplement organizations. Job titles of those executives that will find this program to be most applicable to their job functions include:

- Regulatory Affairs
- Regulatory & Quality
- Regulatory & Labeling
- Quality Assurance
- Legal Counsel
- Compliance

SPONSORSHIP OPPORTUNITIES:

At this time, there are a variety of sponsorship and exhibition opportunities available for companies wishing to increase their visibility and participation in the program, ranging from keynote speaking opportunities through to exhibitor and documentation sponsors. Organizations most suitable for this type of exposure provide services and solutions including:

- Contract Manufacturing Organizations
- Contract Research Organizations
- Labeling & Regulatory Consultants
- Labeling Technology & Development
- Testing & Adulteration Laboratories
- Regulatory Consultants
- Regulatory Database Developers
- Quality Assurance Systems & Software

2016 ATTENDEE COMPANIES INCLUDED:

AMERICAN BOTANICAL COUNCIL
ARBONNE INTERNATIONAL
COUNCIL FOR RESPONSIBLE NUTRITION
COVANCE
FDA
FOOD STATE
GEMINI PHARMACEUTICALS
GRIFFIN INSURANCE SERVICES
HERBALIFE
INTERHEALTH NUTRACEUTICALS
INTERNATIONAL VITAMIN CORP.
ISAGENIX
KEMIN FOOD TECHNOLOGIES
NATURAL PRODUCTS ASSOCIATION
NBTY
NBTY
NELLSON LLC
NEW AVON
NOW FOODS
NUTRABOLT
PFIZER CONSUMER HEALTHCARE
PHARMAVITE
PROVIDENT NUTRACEUTICAL
PURITY PRODUCTS
RECKITT BENCKISER
RIDGECREST HERBALS
SOLVAIRA SPECIALTIES
SWANSON HEALTH PRODUCTS
US PHARMACOPEIA