# DIETARY SUPPLEMENTS: REGULATORY STRATEGY

**NOVEMEBER 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***

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# 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**
*Attorney*
**FEDERAL TRADE COMMISSION (FTC)**

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

**Cara Welsh**
*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**

**Alan Lewis**
*Government Affairs, Stakeholder Relations, Organic Compliance*
**NATURAL GROCERS**

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

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

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

**Brenda VanGoethem**
*Director of Regulatory Affairs and Quality Assurance*
**NATURE'S WAY – SCHWABE NORTH AMERICA**

### 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

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

**Ivan Wasserman**
*Partner*
**ALMIN TALATI UPADHYE**

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

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

# DIETARY SUPPLEMENTS: REGULATORY STRATEGY

## *DAY ONE | MONDAY, NOVEMBER 13*

**8:00 REGISTRATION & WELCOME COFFEE**

**8:45 CHAIRPERSONS OPENING REMARKS**

**9:00 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**

**10:00 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.**

**10:30 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.

**11:00 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 Welsh,** *Senior Advisor, Office of Dietary Supplement Programs*
**CFSAN/FDA**

**11:30 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

**12:00 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 Welsh,** *Senior Advisor, Office of Dietary Supplement Programs*
**CFSAN/FDA**

**12:30 LUNCHEON FOR ALL CONFERENCE GUESTS**

**1:45 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.,** *Partner*
**COLLINS GANN MCCLOSKEY & BARRY PLLC**

**Alan Lewis,** *Govt. Affairs, Stakeholder Relations, Organic Compliance*
**NATURAL GROCERS**

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

**2:30 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**

**3:15 COFFEE & NETWORKING BREAK**

**3:45 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**

**4:30 PROACTIVE EFFORTS ON GMO LABELLING FOR THE DIETARY SUPPLEMENT INDUSTRY**

The dietary supplement industry is guided by oversight from the United States 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 an industry 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,** *Govt. Affairs, Stakeholder Relations, Organic Compliance*
**NATURAL GROCERS**

**5:15 CONCLUSION OF DAY ONE PRESENTATIONS**

# DIETARY SUPPLEMENTS: REGULATORY STRATEGY

## *DAY TWO | TUESDAY, NOVEMBER 14*

**8:45 CHAIRPERSONS OPENING REMARKS**

## TRACK ONE - CLAIMS REGULATION

**9:00 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**

**9:45 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 the most appropriate 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, and 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 L. Hann,** *Attorney*
**FEDERAL TRADE COMMISSION (FTC)**

**10:30 COFFEE & NETWORKING BREAK**

**11:00 CRAFTING ACCURATE AND SUBSTANTIATED CLAIMS FOR DIETARY SUPPLEMENT LABELS**

Executives in the dietary supplement industry are continually investigating the health benefits of nutritional supplements in order to widen the scope of product benefits and potential users of products, and at the same time focus on balancing claims with appropriate substantiation and evidence so as to not provide misleading label claims. Limiting the scope of claims to focus on structure function claims, scientifically supported by research and evidence, organizations will effectively and compliantly label products, ultimately providing guidance to users as well as aligning claims and labels with FDA and FTC regulatory oversight. An assessment and guidance on unsubstantiated claims against those that have been substantiated will provide executives with illustrative examples of effective and compliant claims.

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

**Corey Hilmas,** *SVP of Scientific & Regulatory Affairs*
**NATURAL PRODUCTS ASSOCIATION**

## TRACK TWO - QUALITY & MANUFACTURING REGULATION

**9:00 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**

**9:45 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**

**10:30 COFFEE & NETWORKING BREAK**

**11:00 UPDATES TO SUPPLEMENT SUPPLIER VERIFICATION PROGRAMS ALIGNED WITH FSMA GUIDELINES**

As the FDA continues to strengthen the US food safety system, new rules and procedures within the Food Safety Modernization Act (FSMA) are directly affecting dietary supplement ingredient and supplier quality assurance and oversight, enforcing stricter, scientific preventative control procedures and regulated foreign supplier and supply chain verification. The flexibility and exemptions allowed through section 21 CFR 117 subparts, leaves dietary supplement executives questioning the responsibilities and oversight for implementing these policies and procedures, especially within robust supply chains. An in-depth analysis of the supply chain verification program, HARCP policy and the foreign supplier verification program, all in preparation for compliance dates and site inspections, will clarify expectations for current and future production procedures.

- Interpretation of scientific risk-based controls in manufacturing
- Clarification of expectations under the Foreign Supplier Program
- Overview of exemptions from HARPC and the Supply Chain Program

**Brenda VanGoethem,** *Director of Regulatory Affairs and Quality Assurance*
**NATURE'S WAY – SCHWABE NORTH AMERICA**

**DAY ONE CONTINUED...**

# DIETARY SUPPLEMENTS: REGULATORY STRATEGY

## *DAY TWO | TUESDAY, NOVEMBER 14*

**11:45 INTERNATIONAL TRADE AND MULTI-JURISDICTIONAL ENFORCEMENT FOR DIETARY SUPPLEMENT INGREDIENT IMPORTS**

New ingredients and finished products imported into the U.S are regulated across partnered governmental agencies, who have access to shared data and information needed to regulate dietary supplement products. These imports, often regulated at the border by U.S Customs, must also go through pre-arrival approval regulated by the FDA, USDA and the USFW, each increasing their requests for specific information to support classifications and claims. An analysis of specific case studies featuring integrated federal enforcement and regulatory and trade obligation requirements will highlight the international trade awareness required by the dietary supplement industry.

- Navigate the FDA import procedure and requirements
- Consideration for NDI submissions and overlap with FSMA
- Case studies analyzing trade enforcement regulations

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

**12:30 LUNCHEON FOR ALL CONFERENCE GUESTS**

**1:30 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**

**2:15 CASE STUDY: TESTING & VALIDATION METHODS FOR SUBSTANTIATED CLAIMS**

Given the increasing level of litigation surrounding the dietary supplement industry and claims made regarding products, manufacturers are increasingly aware of the need to provide robust levels of data to substantiate and validate product claims. Beyond legal claims against dietary supplement corporations, many organizations also look to increased testing and verification in order to build trust with consumers, highlighting the purity and safety of products and ensuring no adulteration has taken place. From use of new technologies such as DNA sequencing as well as thorough testing of raw materials to ensure ingredient purity, developing and implementing thorough testing & specification will ensure products match product labels with exactitude.

- Methodologies for product testing & specification
- Legal and regulatory guidance & compliance
- Impact on building safety & consumer trust

**3:00 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**

**3:45 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