

# ANSI DIETARY SUPPLEMENTS STANDARDIZATION COORDINATION MEETING

MAY 13, 2019



# MEETING REPORT



The American National Standards Institute (ANSI) convened this follow-up meeting to a stakeholder event held on December 6, 2018. The purpose was to continue the dialogue among interested stakeholders (manufacturers, retailers, government agencies, trade and professional associations, consumer organizations, and others) on opportunities to work together to advance safety, quality, and trust in the dietary supplements supply chain, particularly through voluntary consensus standards and related conformity assessment programs.



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**ANSI Meeting Report**  
**Dietary Supplements Standardization Coordination Meeting**  
**Monday, May 13, 2019 | 1:00 – 5:00 pm**

20 F Street, NW Conference Center  
Washington, DC

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## **1. Executive Summary**

On May 13, 2019, the American National Standards Institute (ANSI) convened a meeting to discuss opportunities to advance safety, quality, and trust in the dietary supplements supply chain through voluntary consensus standards and related conformity assessment programs, as a component of robust and responsible industry self-regulation and an adjunct to the regulatory framework. The meeting was a continuation of a dialogue begun on December 6, 2018, at an event organized by ANSI and the Global Retailer and Manufacturer Alliance (GRMA). Stakeholders attending included manufacturers, retailers, government agencies, trade and professional associations, consumer organizations, and others.

A key focus of discussion was the interplay between two recent initiatives: 1) a new certification program devised by GRMA against the ANSI/NSF 455-2 standard on good manufacturing practices (GMPs) for dietary supplements, and 2) the Supplement Safety and Compliance Initiative (SSCI) benchmarking guidance documents recently released for public review. Both represent significant steps forward by the dietary supplements industry.

Costly and redundant audits are a significant concern for the industry. A speaker from the National Institute of Standards and Technology (NIST) highlighted best practices in devising effective conformity assessment programs.

A regulatory perspective was provided by a staff member from the Federal Trade Commission (FTC) who described how the agency works cooperatively with the Food and Drug Administration (FDA) to address unfair, deceptive, and unsubstantiated marketing claims about the effectiveness of dietary supplements.

Recognizing the expanding e-commerce market for dietary supplements, a representative of the Global Food Safety Initiative (GFSI) provided an overview of a new e-commerce working group that it has established to mitigate risks associated with e-commerce and food safety.

As a step toward increasing consumer confidence in dietary supplements, a representative of the Pew Charitable Trusts called for more participation by consumer advocates and public health officials in devising standards and conformance programs for dietary supplements and greater transparency in audit reporting.

A key take-away from the meeting was a set of guiding principles of cooperation. High level goals included building consumer confidence in dietary supplements and trust throughout the supply chain, and ensuring the safety, quality, and integrity of dietary supplements and ingredients. Strategies supporting these goals included: ethical practices and good faith efforts to work in the public interest to reduce safety and health risks to consumers; networking, and collaborating on industry solutions and best practices; exchanging data and maintaining information in a publicly available registry; establishing meaningful benchmarks, requirements, and quality outcomes; relying on transparent, open, voluntary consensus standards and technical materials; periodic assessments by competent auditors to measure conformance with these standards; and consumer communication.

## **2. Workshop Background and Overview**

The dietary supplements space is extremely complex. A conservative estimate of the number of dietary supplement products in the market is presently estimated to exceed 55,000. There are several major product categories – multivitamins, sports nutrition, and probiotics for example – with a majority of market value covered by about 100 ingredients. The lack of uniformity of product quality and, in some cases, adulteration of dietary supplements continues to be a concern for manufacturers, regulators and consumers alike.

The industry continues to look for ways to improve trust and confidence in dietary supplements, while minimizing overlapping and duplicative audits. For their part, consumers are looking for greater transparency with respect to dietary supplement ingredients, product label information, and claims. And regulators are seeking to protect public health and safety, maintain product integrity, and support informed decision making by both consumers and health care professionals, without stifling innovation and efficiency in the marketplace.

In ANSI's experience, programs built on robust product and process standards with appropriate risk-based conformity assessment procedures are key to building trust and confidence.

### **Action Items from the December 6, 2018 Meeting**

The May 13, 2019 meeting was a follow-up to a [December 6, 2018 meeting](#) on the same topic. At that meeting, attendees representing a range of stakeholders learned about several industry-led efforts to advance safety, quality, and trust throughout the dietary supplements supply chain. Discussions also highlighted current standards and conformity assessment-related efforts to address quality and related issues. Participants engaged in a lively question and answer session with presenters, and then moved to a moderated discussion of possible opportunities for further collaboration and harmonization and next steps.

At the conclusion of the December meeting, all agreed that ANSI should convene a follow up meeting to advance discussions on greater collaboration. Industry representatives said they wanted to learn about practical ways to deal with "audit fatigue." Participants also said that they wanted to learn about a new e-commerce working group established by GFSI, which was in the formation stages late in 2018. They recommended getting together again in 4-6 months for updates on ongoing efforts and also suggested that a follow up meeting be timed to coincide with other industry events. Finally, all agreed that it would be a good idea to discuss principles of cooperation.

### **Developments since December 2018**

GRMA – a retailer-led initiative – completed the pilot phase of its certification scheme for dietary supplements GMPs. The scheme, now in full operation, is built on both the American National Standards (ANS) process and the international standard for certification scheme owners and is intended to deliver trusted results to both the private and public sectors.

Representatives from the SSCI spoke in December about their plans to provide benchmarks, share best practices, and enforce safety standards throughout the entire dietary supplements supply chain. SSCI – also a retailer-led initiative – issued draft benchmarking guidance documents on March 28<sup>th</sup> and opened a 30-day public comment period on these documents.

In the regulatory space, both the FDA and FTC have been exercising aggressive oversight of industry players who do not act responsibly – specifically, entities marketing potentially dangerous products or making unproven or misleading claims about the health benefits they may deliver. Numerous warning letters and online advisories have been issued since the beginning of this year.

In February, FDA announced the beginning of an effort to revamp its oversight of dietary supplements. As FDA Commissioner Gottlieb noted in his announcement, in the 25 years since Congress passed the Dietary Supplement Health and Education Act (DSHEA), the dietary supplements market has grown significantly. What was once a \$4 billion industry comprising some 4,000 unique products is now an industry worth more than \$40 billion with more than 55,000 different products available to consumers.

The ANSI standardization coordination meeting kicked off a full week of both industry and government events related to the dietary supplements industry. On May 14, 2019, the Dietary Supplement Regulatory Summit, hosted by five major trade associations, continued the discussion and expanded it to include FDA announcements. On May 15<sup>th</sup>, U.S. Pharmacopeia (USP) hosted its annual Dietary Supplements Stakeholders Forum, focused on input to the development of USP standards. And on May 16<sup>th</sup>, the FDA held a public meeting on “Responsible Innovation in Dietary Supplements.”

### **3. Welcome and Opening Remarks**

- Joe Bhatia, President and CEO, American National Standards Institute (ANSI)

Mr. Bhatia welcomed participants, noting the wide array of organizations and interests represented, many of which are new to ANSI and new to the standardization space. This indicates that the topic of the meeting – the role of standards and conformity assessment in advancing safety, quality, and trust in the dietary supplements supply chain – resonates with a wide range of stakeholders, both public and private sector. It touches on issues ranging from labeling, ingredient identity and quality, to supply chain security. Mr. Bhatia added that voluntary consensus standards for products, processes, and services are at the foundation of the United States’ economy and society. The U.S. has a proud tradition of developing and using voluntary standards to support the needs of our citizens and the competitiveness of U.S. industry in world markets.

#### **Introduction to ANSI**

Mr. Bhatia provided a brief overview of ANSI. The Institute represents the interests of more than 270,000 companies and organizations and 30 million professionals. ANSI members include government agencies, trade associations, standards developing and conformity assessment organizations, professional societies, companies, academic and international bodies, and consumer organizations.

As the voice of the U.S. standards and conformity assessment system, ANSI empowers its members and constituents to strengthen the U.S. marketplace position in the global economy while helping to assure the safety and health of consumers and the protection of the environment. ANSI does this in part through its role as the official U.S. member of the International Organization for Standardization (ISO) and, through the U.S. National Committee, the International Electrotechnical Commission (IEC). The Institute promotes the use of U.S. standards internationally, advocates U.S. policy and technical positions in international and regional standards organizations, and encourages the adoption of international standards as national standards where they meet the needs of the user community.

ANSI oversees the creation, promulgation, and use of tens of thousands of norms and guidelines that directly impact businesses and consumers in nearly every sector: from acoustical devices to construction equipment, from dairy and livestock production to energy distribution, and many more. Although ANSI itself does not develop standards, it provides all interested U.S. parties with a neutral venue to come together and work towards common agreements. The ANS process to create these voluntary standards is guided by the Institute's cardinal principles of due process, openness, and consensus in standards development.

The Institute ensures that access to the standards process, including an appeals mechanism, is made available to anyone directly or materially affected by a standard that is under development. Thousands of individuals, companies, government agencies and other organizations such as labor, industrial and consumer groups, voluntarily contribute their knowledge, talents and efforts to standards development.

ANSI is also actively engaged in accreditation through its wholly owned subsidiary ANAB, the ANSI National Accreditation Board, assessing the competence of organizations determining conformance to standards. ANAB accreditation provides assurance that standards, goods, services, and people meet essential requirements throughout the global supply chain, engendering consumer trust and fostering competitiveness. Increasingly, procurement authorities, government agencies, and program/scheme owners are specifying accreditation in order to demonstrate the technical competence and impartiality of conformance services and processes.

In sum, standards and conformity assessment play a tremendous role in our daily lives, as well as in market access and trade issues. ANSI is invested both in the integrity of the U.S. standardization system and in supporting the market-driven nature of that system.

Mr. Bhatia reviewed the action items from the December meeting and what has happened since that meeting. He noted, "This follow-up gathering provides a clear opportunity for the private sector to take the lead with respect to voluntary, self-regulatory actions, in support of flexible, light touch regulation. ANSI looks to the assembled stakeholders to identify what needs to be done, and in what priority order, to address the challenges to safety, quality, and trust in the dietary supplements supply chain."

Mr. Bhatia closed by re-emphasizing that ANSI promotes the broad benefits of the voluntary consensus standards process, supported by internationally recognized conformity assessment programs. A key part

of the meeting will be to see how the various stakeholder efforts and initiatives can best collaborate to deliver the certainty and confidence that regulators, industry, and consumers are looking for in the dietary supplements space. Mr. Bhatia encouraged active participation by all present on how best to move forward in a coordinated fashion. He apologized that other business travel commitments required him to leave early.

#### **4. Industry Activity Updates**

##### **4.1 Global Retailer and Manufacturer Alliance (GRMA) certification scheme**

- Randy Slikkers, CEO, GRMA, and Michael Finamore, Chairman, GRMA Governance Board and CEO of Gemini Pharmaceuticals, Inc.

Mike Finamore explained that GRMA wanted to create a single audit scheme for dietary supplements, along with over-the-counter (OTC) drugs and cosmetics. The idea was to eliminate redundant audits and to have a clear and consistent audit process that auditors could be trained on. To achieve that goal, they created a set of public standards working through NSF International. The committee comprised public health officials, manufacturers, retailers, and others. The documents were developed under the ANS process, following ANSI's essential requirements for due process, openness, consensus, public comment, etc. The standards were published as ANS in December 2018 under the NSF-455 umbrella. Mr. Finamore stated that the ANS designation is the "top tier" of a "public" standard and will enhance consumer trust, compared to a "private" standard where it may not be clear what went into creating it. GRMA has developed an auditor training program for certification against the standards.

Randy Slikkers said the GRMA GMP standard and related certification scheme will benefit all stakeholders. GRMA considered current auditor qualifications and industry trends. There was not a lot of data available and GRMA wanted to see what it could do to help. The standard provides a level of control over all facets of the audit process including certification bodies (CBs). All CBs who will be conducting audits to the standard are required to go through GRMA training. GRMA feels that the standard and the certification program have created a level playing field that will provide tremendous value to the industry. GRMA plans to put out an annual industry report card. Mr. Finamore added that having a single audit to a high standard is desirable, consistent with the goal of reducing redundant audits, and will benefit retailers and manufacturers.

In terms of what's next, the GRMA program is being mandated by key retailers for OTC drugs and cosmetics. Dietary supplements will be next. GRMA is looking at where the community next wants to go, and how stakeholders can help direct the future of these efforts. Most manufacturers will do an internal gap analysis. They can also engage a member CB to do a preliminary audit to enable corrective action. A further step would be to schedule a full certification audit. Scores will be shown on the ReposiTrak website.

GRMA invited people to come to its August summit to help them understand how retailers and GRMA can bring this process forward.



- [View GRMA's presentation](#)

#### **4.2 Supplement Safety & Compliance Initiative (SSCI) benchmarking efforts**

- Dadrion Gaston, Senior Director Food Safety & Health, Walmart

Ms. Gaston explained that SSCI is an industry driven initiative led by retailers to enhance the safety and compliance of dietary supplements throughout the entire supply chain. The initiative creates a harmonized benchmarking process to recognize standards and best practices, delivering equivalence and convergence of supplement safety systems globally. SSCI allows the industry to proactively identify areas of risk throughout the dietary supplement supply chain and establish guidance to drive continuous improvement in safety standards. In process and structure, it is similar to GFSI.

Ms. Gaston added that a harmonized benchmarking process helps to enhance customer safety and reduces audit redundancy. Ultimately, it's all about the customer because without consumers there would be no dietary supplements industry.

SSCI released its benchmarking and guidance documents for comment on March 28. They deal with GMP and technical guidance for finished product manufacturing. The comment period ended on May 1st. Ms. Gaston confirmed that the comments were presently being collected and reviewed, and within a few weeks the guidance will go back to the SSCI board for ratification.

SSCI has 6 working groups (WGs) on raw materials, probiotics, and other facets of the supply chain. They are reviewing existing standards and the science behind them for gaps. For example, one WG deals with botanical raw ingredients in food while another is looking at animal sourced raw materials (e.g., glucosamine). They are also looking at packaging and product stability.

Next steps will include Board acceptance of the benchmarking and technical guidance document. As the WGs finish their work, their input will be added to the technical guidance document. SSCI will then invite certification program owners (CPOs) to benchmark against the documents. The documents, including announcements and benchmarking applications, are available on the SSCI website. More involvement is welcome.

- [View SSCI's presentation](#)

#### **5. Approaches to Optimize Assessment. Resources and Results: What Works & What are the Issues?**

- Gordon Gillerman, Director, Standards Coordination Office, National Institute of Standards and Technology (NIST)

Mr. Gillerman explained that the NIST standards coordination office helps federal government agencies design approaches to conformity assessment systems to meet their needs. For example, the current design of the Energy Star process was created at NIST. NIST also has worked with law enforcement

officials on certification of body armor. In addition, NIST was also involved in the establishment of FedRAMP, a program that allows cloud computing service providers to demonstrate that they meet security control requirements. Finally, NIST is working with the FDA's Center for Devices and Radiological Health to reduce the turnaround time for clearance of medical devices. NIST is part of the U.S. Department of Commerce and is not a regulator.

Mr. Gillerman observed that, when devising a conformity assessment program, it is important to think about what are the industry requirements that the product needs to be built to. It is best to avoid mutually exclusive technical requirements that drive up costs. Similarly, the regulatory and market requirements should also be considered.

Mr. Gillerman indicated that risks associated with nonconformity should drive the rigor of the conformity assessment system. He personally worked on radiation detectors for homeland security operations where the consequences of products not performing as intended are catastrophic. On the other hand, over designing a conformance system can result in wasted money. The key is to be able to provide enough confidence to the customer. Marketplace consequences (penalties) and the ability to initiate effective recalls will reduce the level of rigor needed for the conformity assessment system. The goal of achieving safe and trusted products in the marketplace should be kept in mind.

There is a body of internationally accepted standards that are the basis for doing conformity assessment. The standards provide flexibility on the various parts of the conformity assessment system. Mr. Gillerman commented that it is good to see the individual competency of dietary supplements assessors is being assessed, and the benchmarking that is being done will help. He suggested that standardizing the reporting may also be something to consider. Conformity assessment methods should not be conflated with the technical requirements for products and processes.

NIST endeavors to share knowledge online. There was a revision to OMB circular A-119 in January 2016 which guides federal agencies on their use of standards and in conformity assessment. NIST also has two special publications on conformity assessment. NIST helps government agencies to leverage what the market is doing. Active stakeholder engagement is also an effective way to promote common understanding.

➤ [View NIST's presentation](#)

## **6. Stakeholder Perspectives: Issues in Building Trust and Confidence**

### **6.1 Hot Topics and Law Enforcement Trends in the Dietary Supplements Industry**

➤ Carolyn L. Hann, Chief of Staff for Advertising Practices, Bureau of Consumer Protection, Division of Advertising Practices, Federal Trade Commission (FTC)

Ms. Hann presented next, noting that her remarks were her own, not those of the FTC or any individual commissioner. She described FTC as the nation's only general jurisdiction consumer protection agency,

covering topics from health to telemarketing. The agency's broad mandate is to stop unfair or deceptive acts and practices in commerce. It looks at all forms of marketing and advertising.

With respect to food, including dietary supplements and OTC drugs, FTC's authority overlaps with FDA. FTC's authority is primarily over advertising, while FDA's is over labeling. FDA has exclusive jurisdiction over prescription drugs and prescription devices. FTC operates under a different legal framework than FDA. FTC is primarily a law enforcement agency rather than a regulatory agency. It is not involved in the premarket approval process. It does not approve ads or claims in advance, nor does it make any distinction between product categories. It interacts regularly with FDA. FTC staff are lawyers and economists, not scientists. FTC generally defers to FDA on matters of safety, content, and purity of dietary supplements and OTC drugs.

FTC looks at unfounded claims under sections 5 and 12 of the FTC Act that, respectively, prohibit unfair or deceptive practices in commerce and the dissemination of false and misleading ads. Essentially, they look at what claims are conveyed and are they substantiated. The agency's perspective is what would a reasonable consumer conclude from an ad, including expressed versus implied claims. They consider the overall net impression of an ad. Tiny print that cannot be read is not an effective disclosure. FTC asks is there competent and reliable scientific evidence supporting the claims; in other words, if the claims are substantiated by data. This usually requires high quality clinical trials. Studies should not be looked at in isolation; rather, all relevant evidence should be considered.

A recent case involved POM Wonderful pomegranate juice and a related dietary supplement. The company made claims about arterial plaque, cancer, and erectile dysfunction. The FTC and the DC circuit court confirmed the FTC staff's finding that the POM Wonderful ads only included the favorable test results, but not all of them. In summary, the product and claims should match the science.

Another recent case involved CellMark which targeted cancer patients suffering from side effects to take Cognify tablets and CellAssure nutritional drink mix. The company had no clinical studies to support its claims. The FTC settled against the company and its president/CEO. This is a good example of the FDA and FTC having overlapping jurisdiction. The FDA had sent the company a warning letter for violation of the Food, Drug, and Cosmetics Act. The company's president was serving an 18<sup>th</sup> month prison sentence for criminal misconduct relating to another matter while the FTC was trying to negotiate a civil settlement with them.

Another case involved NextGen Nutritionals who made claims that their products would help to burn fat and combat deadly diseases. FTC entered into a partially suspended judgment of \$1.3 million with the company and found seven false claims. The company's website included an "Ethical Site" seal that falsely claimed an independent third party certified it.

Other cases included one with Catlin Enterprises and a product called Withdrawal Ease that claimed to help deal with opioid addiction. In another case, FTC found that Nobetes Corp. made false, unsubstantiated claims marketing a pill that claimed to treat diabetes. The ads used an actor who

pretended he was a medical professional. FTC had sent a warning letter to Nobetes Corp, two years before they eventually settled with them. Ms. Hann cautioned not to ignore warning letters.

FTC often coordinates with FDA. The agencies jointly issued warning letters to three companies in February of 2019 for some supplements that claimed to treat Alzheimer's disease. FDA concluded these were drugs and were misbranded. FTC expressed concern that the claims made were not adequately substantiated. In March of 2019, the two agencies issued letters to three marketers of cannabidiol (CBD), citing similar concerns.

The Business.ftc.gov website includes guidance documents for further information.

- [View FTC's presentation](#)

## **6.2 E-Commerce and its Impact on Safety**

- Rishi Banerjee, Senior Manager, Global Food Safety Initiative (GFSI)

Mr. Banerjee described the history of how GFSI came into being. In the 1990s, there were prominent food safety outbreaks, which were very concerning to a large group of retailers. CEOs came together to address these with manufacturers and GFSI was born in the year 2000. The organization is based in Paris and has offices around the world. GFSI is about harmonizing and setting standards for food manufacturing and retail spaces, primary production through distribution. The vision is safe foods for consumers everywhere. GFSI is a benchmarking entity. It does not conduct audits but it works with CBs, accreditation bodies, CPOs, and others in the supply chain. Mr. Banerjee stated that GFSI is recognized as the "gold standard" for food safety around the world.

The GFSI Board sets priorities on what working groups will work on, looking at risk factors up and down the supply chain. A Local Technical WG on E-commerce (LTWG) for food safety was established in January 2019, e-commerce being a growing area that is very important for industry. There are currently 13 stakeholders involved representing a very diverse group of people with an interest in the e-commerce space. The focus is on mitigating risks associated with food safety e-commerce, looking at all of the entities involved and the steps in the supply chain.

- [View GFSI's presentation](#)

## **6.3 Assuring Accountability and Transparency in Benchmarking and Certification Schemes**

- Sandra B. Eskin, Director, Safe Food Project, Pew Charitable Trusts

Ms. Eskin described Pew's work, noting that its policy priorities include work on 40 projects. This includes supporting efforts to work on marketplace initiatives. Pew has programs in a wide range of industries to help fill gaps where government oversight is lacking. From Pew's perspective, there are many standards and third party oversight programs. Conflicts of interest are a concern, and training for auditors is important.

Ms. Eskin noted that the FDA's Food Safety Modernization Act provides a direction for third party certification programs, the voluntary qualified importer program. It does so for products that need high risk food safety certification. It speaks to the importance of qualified food safety auditors.

In sum, third party auditor programs have an important role to play. However, Pew has two major concerns. First, Pew does not see any involvement in the governance and standards development of these programs by consumers and public health advocates. Their input needs to be incorporated and Pew appreciates how challenging this can be. A second concern is that consumer advocates do not have access to audit reports. Pew recognizes there are privacy and confidentiality considerations. Still, an effort should be made to incorporate these perspectives in food safety governance and standards setting.

- Pew Charitable Trusts did not use presentation slides.

## **7. Moderated Discussion with Panelists and Audience**

- Mary Saunders, Vice President for Government Relations and Public Policy, ANSI

Ms. Saunders led the group in an open Q&A session based on the presentations just heard. Comments included the following:

- There is discussion in the supplements space about the need for some sort of mandatory product listing with FDA. It could provide assurance to stakeholders. It would likely require legislation.
- Who are the consumers of conformity assessment information? There may be three: regulators, supply chain participants, and consumers themselves. Giving the consumer a technical audit report may not be valuable. However, professional consumer advocates are interested. There are groups that work to ensure that consumer concerns are addressed.
- Might FDA grade manufacturers, suppliers, retailers? Such a level of comprehensive inspections doesn't happen today and is not likely, so private systems are needed to augment it. The reality is that consumers assume that products have been inspected.
- E-commerce labeling is relevant for both food safety and dietary supplements. The person selling the product may not be the manufacturer. Taking ownership of labeling is important for manufacturers.
- What are the best practices as far as FTC is concerned? It is important to think about advertising campaigns and how messages can be reasonably interpreted. Companies should have good compliance staff in house. They should also have substantiation on hand before making a claim. The claims should match the science. Companies should be aware of FTC guidance and how to interpret section 5 of the FTC Act, especially if they want to have a celebrity endorsement or a testimonial.
- With respect to recalls, risk management and confidence are key. Regulators will look at the effectiveness of a recall while retailers will look at the supply chain financial cost. Recalls can



reduce the rigor of conformity assessment needs. FDA has mandatory recall authority for food.

- What is the scope of the ANSI/NSF 455-2 standard? The 455 series of standards cover GMPs for OTC drugs (455-4), cosmetics (455-3), and dietary supplements (455-2).

## 8. Moderated Open Discussion of Draft Principles of Cooperation

- Moderators: Alain Turrene, Vice President Corporate Social Responsibility, Walgreens and Gillian Kelleher, Vice President of Food Safety & Quality Assurance, Wegmans<sup>1</sup>

The moderators led the participants in a discussion of draft principles of cooperation (**Appendix 3**) that were provided as part of the meeting program, with consideration given to how they relate to the GRMA and SSCI efforts. This was not an attempt to obtain individual organizational commitments of support but rather to get a sense of the group as a whole. Discussion focused first on the adequacy of the draft goals and proposed changes and then moved on to a similar review of the draft strategies to achieve these goals. Points raised included those listed below.

### Draft Goals

1. To ensure the safety, quality, and efficacy of dietary supplements.
  - Say “authenticity” instead of “efficacy”?
  - Talk about the “substantiated benefits” of dietary supplements?
  - Say “identity” instead of “efficacy” or “authenticity”?
2. To ensure that claims made about dietary supplements are truthful and not misleading.
  - This is an obvious goal but, other than the FTC presentation, there has not been discussion of claim substantiation from a scientific standpoint.
  - This is on an SSCI list of potential work groups but the current six work groups are not addressing it specifically at this time. But, yes, products must meet potency and content claims and be authentic, not adulterated, etc.
  - GRMA and its audit scheme is specific to current GMP requirements. That would not really entail an investigation into claims, efficacy, or potency. Certainly, the more granular an audit is, the more certain issues are considered. But that is not the purpose of what the GRMA is trying to provide.
  - The draft goals are not saying that any of the standards or related certification schemes necessarily cover these elements. It is more asking the question could standards and certification programs provide an underpinning for truth in advertising.
  - We should be cautious about this second principle. Efficacy or making claims about products is a much more amorphous area than trying to assure quality standards, purity, identity, potency, etc. Those are easier than trying to develop industrywide standards for when something is proven to be substantiated for whatever claims are being made. There are efforts out there by the NPA Foundation et al. looking at unlawful claims. However, if it is

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<sup>1</sup> Mr. Turrene and Ms. Kelleher noted that they are both members of the ANSI Board of Directors and the GFSI Board of Directors.

- going to take the focus off goals 1 and 3, it might be better to address those first before looking at goal 2.
3. To build consumer confidence in dietary supplements and trust throughout the supply chain
    - This is probably the number one goal that we are working toward.
    - Perhaps an additional goal needs to be to commit to work together toward a self-regulatory structure, to set aside competitive differences as organizations and groups of stakeholders.
    - How are we letting the market know what we are doing? It needs to be conveyed that there is broad industry participation in this effort.
    - Certainly, networking and collaborating on industry solutions are strategies to achieve the goals.
    - There must be concerted education of consumers across the industry. In order to build trust and confidence, the products must actually be safe.
    - Looking at the supply chain is extremely important.
    - Supply chain confidence has grown over the past 20 years. GFSI is looking at things like e-commerce that did not exist back then. There have been improvements.

Comments on the draft strategies included those noted below.

### **Draft Strategies**

Components of robust and responsible industry self-regulation aimed at achieving these goals include the following:

1. Ethical practices and good faith efforts to work in the public interest to reduce safety and health risks to consumers
2. Networking, and collaborating on industry solutions
  - Is this a strategy? Is it actionable? That's why we are here.
  - Add "and best practices"? This meeting is an effort to develop best practices. Add "industry speaking with one voice"?
  - Not to the exclusion of others in the room but there needs to be collaboration to discuss what GRMA and SSCI are doing to help bring the industry to a new level.
  - There was a similar experience with E. coli where it didn't matter that some suppliers weren't affected – consumers were not buying spinach, and the industry had to come together. Let's learn from other sectors.
3. Exchanging data and maintaining information in a publicly available registry
4. Establishing meaningful benchmarks, requirements, and quality outcomes
5. Reliance on transparent, open, voluntary consensus standards
  - What is meant by voluntary, consensus standards?
  - There is a definition in OMB circular A-119. This means that they are developed through a process that is open, transparent, involves all materially interested and affected parties, tries to achieve balance, lack of dominance, has procedures to reach consensus, is characterized by due process, etc.
  - USP standards are public, voluntary standards developed by an expert committee in an open, transparent, due process manner. Though not the same as the ANSI process, they have a place.

6. Periodic assessments/audits to measure conformance with these standards
  - What about auditor competency? Where does that fit in?
7. Reducing duplicative audits
  - Maybe take this off the table. This is a goal, not a strategy.

Additional suggestions:

- Add a new bullet on consumer communication? So that that they will invest their dollars in quality supplements with quality retailers.
- Say something about definitions so there is a common understanding of language?

Discussion then turned to what steps are those in the room taking to implement the strategies.

Comments included the following:

- SSCI is trying to build a neutral platform for collaboration like GFSI. It is developing guidance, not a standard. It is not an association in and of itself. The industry should come together and work collaboratively as associations. Perhaps work with the larger food industry? The dietary supplements industry is very small and the same experts are at the table for all the different industries.
- GRMA agrees that a lot of energy is being spent trying to get to the same place. GRMA is not just a dietary supplements organization. It sees the standards development process as key to the industry evolving. It would like to collaborate with SSCI on recognition of the GRMA standard as the threshold. The standard can be improved over time. GRMA is proud of the work put into it. If the GMP is resolved, why spend more money and time doing it over, and over again?
- For those not involved in SSCI or GRMA, what are you hearing? We may not have everyone in the conversation.
- From the store brand perspective, we have a robust program for all of our store brand products, label claims, safety, etc. There's always room for improvement. On the national brand side, there is less visibility and strength to push standards but we hear rumblings that they have concerns with supplements. They see the recalls, hear about the warning letters, etc. We should investigate further with them.
- From a pharmaceutical perspective, we're all here for the same reason, to ensure that dietary supplements are safe and trusted. The challenge lies in different approaches to things. Make the draft principles smart, focused and clear to get us all onto the same page and reach common ground faster.
- Is GRMA saying it should be the only standard out there? No, it should not be the only standard, but if it is proven to be superior to other ones out there, it should be the one we should aim for. Let's use it as the basis of other things.
- Agree GRMA is an excellent GMP standard. How can it be benchmarked with other GMP global standards? That's why SSCI wanted a benchmarking process. Some other sectors of the supply chain have GFSI recognition for ingredients. That's where further conversations with GFSI and the Consumer Goods Forum can help to align better.
- All of these ideas are good. We need public standards, benchmarking, and the capacity to look at the entire supply chain. The question is how to put this all together. We've got the components of it: a standard, a benchmarking effort, lessons learned from food safety. Maybe

there isn't one organization to do it. Maybe it is a group of entities forming a partnership with defined roles.

- GFSI provided a blueprint that helped structure SSCI. The purpose of GFSI wasn't that there was one standard but it provided an architecture for certification/accreditation that served the industry well. We hope that GRMA benchmarks its standard soon.
- Assuming that GRMA could satisfy a benchmark requirement for finished goods conversion, could we look at other parts of the supply chain to address the consumer confidence part of the equation?
- SSCI has other WGs (botanicals, ingredients, raw materials, botanical processing from the farm all the way through). They are almost there in terms of releasing technical guidance. There are many standards out there being evaluated. Please participate in those WGs. Probiotics are up and coming. The list of WGs isn't reflective of all the different sectors of the supply chain.
- From the branded side, there are still significant hurdles in selling to retailers, e.g., the regulatory status of ingredients, test results, etc. This is a great opportunity for GMP and supply chain but there are these other layers.
- Don't build a product specification into the standard.
- What aspect of the consumer's trust are we overlooking or under communicating? What builds consumer confidence over time?
- There's strength in numbers. We're all consumers. Take on best practices over time.

Discussion then turned to potential next steps as a result of today's conversation. Comments included the following:

- Let's get the raw materials taken care of.
- Ensure the quality and identity of dietary ingredients throughout the supply chain should be a goal. The ingredients must be clean in order for the supplement to be clean.
- Is the goal to inspire trust in the entire industry or certain companies that are high quality? Hopefully, it's the entire industry, all of us.
- This is where a registry is important. Many people are not on board. Who will enjoy the fruits of your labor?
- We're trying to raise the bar on the audits, on the suppliers. To weed out the unscrupulous suppliers and the bad actors.
- Agreed, but we also don't want to create barriers to entry. We acknowledge there are some products that aren't as well vetted as desirable. Having a higher standard across the industry for ingredients and how they are processed will instill consumer confidence, and confidence in the industry as a whole.
- This dialogue was refreshing. This is how to move it forward. ANSI's expertise lies in the consensus-building, collaborating, and pulling it together.

## 9. Conclusions and Next Steps

- Mary Saunders, Vice President for Government Relations and Public Policy, ANSI

Mary Saunders thanked the speakers, moderators, and audience for their participation. She offered apologies on behalf of Joe Bhatia who had to leave early to catch a flight to Berlin and on behalf of Fran Schrotter who was unable to attend because of illness.

The contributions from the meeting will be taken back to the ANSI Board of Directors. Some work needs to be done to clarify how the industry efforts fit together, especially GRMA's certification scheme and the SSCI benchmarking effort. The GRMA standard offers a strong benchmark for GMP for finished goods conversion. It goes beyond the minimum requirements set forth in regulation. And it was developed under the ANSI process which includes public comment in addition to the technical committee's deliberations.

In terms of key points that she had heard, Ms. Saunders noted the need to nail down raw materials. USP is active in raw materials, standards of identity, monographs, and reference materials. These other technical documents should be looked at as well. Branded companies want a more coherent list of the issues to focus on first. There was a plea for greater transparency from the consumer perspective. Producing audit reports may be a bridge too far but there are efforts underway for transparency. There should be greater educational outreach and more visibility of what is happening and what is needed.

The top goal is to build consumer confidence in dietary supplements and trust throughout the supply chain including dietary ingredients. Consumer education is an important part of that. The second goal is to ensure the safety, quality, and integrity of dietary supplements and ingredients. Reducing duplicative audits should be a sub goal as well.

Ms. Saunders commented that this is not the end. It is just the beginning. She invited participants to take up the challenge.



## Appendix 1. Meeting Agenda

### May 13, 2019 ANSI Dietary Supplements Standardization Coordination Meeting

#### Networking Lunch | 12:00 noon – 1:00 pm

#### Welcome and Opening Remarks | 1:00 pm – 1:10 pm

- **American National Standards Institute (ANSI)**, Joe Bhatia, President and CEO
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#### Industry Activity Updates | 1:10 pm – 1:45 pm

- **Global Retailer and Manufacturer Alliance (GRMA) certification scheme**, Randy Slikkers, CEO, GRMA, and Michael Finamore, Chairman, GRMA Governance Board and CEO of **Gemini Pharmaceuticals, Inc.**
  - **Supplement Safety & Compliance Initiative (SSCI) benchmarking efforts**, Dadrion Gaston, Senior Director Food Safety & Health, **Walmart**
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#### Approaches to Optimize Assessment Resources and Results: What Works and What are the Issues? | 1:45 pm – 2:00 pm

- **National Institute of Standards and Technology (NIST)**, Gordon Gillerman, Director, Standards Coordination Office
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#### Stakeholder Perspectives: Issues in Building Trust and Confidence | 2:00 pm – 2:45 pm

- **Hot Topics and Law Enforcement Trends in the Dietary Supplements Industry**
    - **Federal Trade Commission (FTC)**, Carolyn L. Hann, Chief of Staff for Advertising Practices, Bureau of Consumer Protection, Division of Advertising Practices
  - **Assuring Accountability and Transparency in Benchmarking and Certification Schemes**
    - **Pew Charitable Trusts**, Sandra B. Eskin, Director, Safe Food Project
  - **E-Commerce and its Impact on Safety**
    - **E-Commerce Working Group, Global Food Safety Initiative (GFSI)**, Rishi Banerjee, Senior Manager
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#### Moderated Discussion with Panelists and Audience | 2:45 pm – 3:15 pm

- **ANSI**, Mary Saunders, Vice President for Government Relations and Public Policy
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#### Networking Break | 3:15 pm – 3:30 pm

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**Moderated Open Discussion of Draft Principles of Cooperation | 3:30 pm – 4:30 pm**

- **Walgreens**, Alain Turenne, Vice President Corporate Social Responsibility
- **Wegmans**, Gillian Kelleher, Vice President of Food Safety & Quality Assurance

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**Conclusions and Next Steps | 4:30 pm – 4:45 pm**

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**Networking Reception | 4:45 pm – 6:00 pm**

## Appendix 2. Meeting Attendees

### May 13, 2019 ANSI Dietary Supplements Standardization Coordination Meeting

First Name	Last Name	Organization
Bill	Steadman	AIB International
Jane	Wilson	American Herbal Products Association (AHPA)
Anthony	Quinn	ASTM International
Jennifer	Boyd	Atrium Innovations
Rishi	Banerjee	The Consumer Goods Forum
Jay	Sirois	Consumer Healthcare Products Association (CHPA)
Gisele	Atkinson	Council for Responsible Nutrition (CRNUSA)
Megan	Olsen	
Karen	Gwozdowski Gauvin	CVS Health
Sean	Campbell	Denison Pharmaceuticals
Carolyn	Hann	Federal Trade Commission (FTC)
Sylvester	Mwazama	
Mike	Finamore	Gemini Pharmaceuticals
Sutapa	Chakraborty	GlaxoSmithKline Consumer Healthcare
Alice	Welenc-Masters	
Carolyn	Zlogar	
Randy	Slikkers	Global Retailer and Manufacturer Alliance (GRMA)
Annette	Graham	Mary Kay
Daniel	Frey	McLarty Associates
Evan	Sarris	National Association of Chain Drug Stores
Shaunice	Wall	National Consumers League
Gordon	Gillerman	National Institute of Standards and Technology (NIST)
Daniel	Fabricant, Ph.D.	Natural Products Association
Ryan	Flood	
Corey	Hilmas, M.D., Ph.D.	
Christine	Yeo	
Brenda	Van Goethem	Nature's Way
Harold	Chase	NSF International
Lisa	Glymph Lattimore	
Jessica	Slomka	
David	Trosin	
Michael	Bradley	Nutra Manufacturing
Leila	Saldanha	NutriIQ LLC
Sandra	Eskin	The Pew Charitable Trusts
Jeffrey	Hamilton	Pfizer
Paul	Bolar	Pharmavite
Russell	Michelson	RB
Taylor	Wallace	Think Health Group
Chris	Aiyer	Underwriters Laboratories, Inc. (UL)

Patricia	Deuster, Ph.D., M.P.H.	Uniformed Services University (USU), Department of Military and Emergency Medicine
Amy	Eichner	U.S. Anti-Doping Agency (USADA)
Charlie	Rast	U.S. Department of Commerce
Carrie	Harney	U.S. Pharmacopeia (USP)
Nandakumara	Sarma	
Amy	Sonderman	
Julia	Love	Walgreens Boots Alliance (WBA)
Alain	Turenne	
Dadrion	Gaston	Walmart
Betsy	Crater	Wegmans Food Markets
Gillian	Kelleher	
Joe	Bhatia	American National Standards Institute (ANSI)
Kelley	Cox	
Reinaldo	Figueiredo	
George	Gulla	
Priscilla	Magee	
Jim	McCabe	
Mary	Saunders	
Lucy	Yarosh	

### **Appendix 3. Draft Principles of Cooperation – Pre-Meeting**

#### **Draft Guiding Principles of Cooperation on Dietary Supplements**

##### **GOALS:**

- To ensure the safety, quality, and efficacy of dietary supplements
- To ensure that claims made about dietary supplements are truthful and not misleading
- To build consumer confidence in dietary supplements and trust throughout the supply chain

##### **STRATEGIES:**

Components of robust and responsible industry self-regulation aimed at achieving these goals include the following:

- Ethical practices and good faith efforts to work in the public interest to reduce safety and health risks to consumers
- Networking, and collaborating on industry solutions
- Exchanging data and maintaining information in a publicly available registry
- Establishing meaningful benchmarks, requirements, and quality outcomes
- Reliance on transparent, open, voluntary consensus standards
- Periodic assessments/audits to measure conformance with these standards
- Reducing duplicative audits



## **Appendix 4. Principles of Cooperation – Post Meeting**

### **Guiding Principles of Cooperation on Dietary Supplements (As Amended at May 13, 2019 ANSI Dietary Supplements Meeting)**

#### GOALS:

- To build consumer confidence in dietary supplements and trust throughout the supply chain
- To ensure the safety, quality, and integrity of dietary supplements and ingredients

#### STRATEGIES:

Components of robust and responsible industry self-regulation aimed at achieving these goals include the following:

- Ethical practices and good faith efforts to work in the public interest to reduce safety and health risks to consumers
- Networking, and collaborating on industry solutions and best practices
- Exchanging data and maintaining information in a publicly available registry
- Establishing meaningful benchmarks, requirements, and quality outcomes
- Reliance on transparent, open, voluntary consensus standards and technical materials
- Periodic assessments by competent auditors to measure conformance with these standards
- Consumer communication