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UNPA
UNITED NATURAL PRODUCTS ALLIANCE

April 29, 2011

Ms. Patricia M. Kuntze
Office of External Affairs
U. S. Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 5322
Silver Spring, MD 20993

Re: FDA Food Safety Modernization Act: Title III – A New Paradigm for Importers; Public Meeting (Notice of public meeting; Request for comment) 76 *Fed. Reg*. 13643 - 13645 (March 14, 2011). Docket Nos. FDA-2011-N-0134; FDA-2011-N-0143, FDA-2011-N-0144; FDA-2011-N-0145, and FDA-2011-N-0146

Dear Ms. Kuntze:

The Standardized Information on Dietary Ingredients (SIDI™) Working Group ("Working Group") is a group composed of dietary supplement firms and industry trade associations. Beginning in 2006, the Working Group initiated the development of a voluntary protocol to streamline information exchange among dietary supplement manufacturers and their raw material suppliers. The Working Group has expanded its work to address the broader issue of supplier qualification, which is a requirement in the dietary supplement current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements (cGMPs, 21 CFR Part 111)[1]. The Working Group has developed a series of voluntary guidelines to assist component suppliers and dietary supplement manufacturers with the supplier qualification process. These guidelines, some of which are in the development process, are intended to serve as templates on which manufacturers can base their own supplier qualification programs. The Working Group is comprised of dietary supplement manufacturers and component suppliers that are members of one or more of the following trade associations: the Consumer Healthcare Products Association (CHPA)[2], the Council for Responsible Nutrition (CRN)[3], and the United Natural Products Alliance (UNPA)[4]. In addition, members of the American Herbal Products Association (AHPA)[5] and the Natural Products Association (NPA)[6] have contributed to the development of the voluntary guidelines.

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[1] 21 CFR Part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements; Final Rule Petition To Request an Exemption From 100 Percent Identity Testing of Dietary Ingredients; Interim Final Rule. Accessed from http://edocket.access.gpo.gov/2007/pdf/07-3039.pdf on April 27, 2011.
[2] CHPA was founded in 1881 and is the national trade association that represents manufacturers and distributors of over-the-counter (OTC) medicines and dietary supplement products (www.chpa-info.org).
[3] CRN is a Washington-based trade association representing ingredient suppliers and manufacturers in the dietary supplement industry (http://www.crnusa.org).
[4] UNPA is an association of dietary supplement and functional food companies that share a commitment to provide consumers with natural health products of superior quality, benefit and reliability (http://www.unpa.com).
[5] AHPA is a national trade association that is focused primarily on herbs and herbal products (www.ahpa.org).
[6] NPA is a national trade association dedicated to the natural products industry (www.npainfo.org).

The Working Group appreciates the opportunity to provide comments in response to the U.S. Food and Drug Administration's (FDA) March 14, 2011 *Federal Register* notice announcing the public meeting and request for comments on the Food Safety Modernization Act: Title III – A New Paradigm for Importers[7]. The Working Group concurs with Commissioner Dr. Margaret Hamburg's December 15, 2010 letter[8] to the dietary supplement industry which identified establishing a strong program of qualifying raw material suppliers, testing incoming ingredients, and verifying the contents of finished products as important steps to reduce the risks of contamination, adulteration, or other supply chain failures. As the global supply chain becomes more complex, proper supply chain management is critical. A robust testing program must be balanced with knowledge of the ingredient suppliers' quality practices. The Working Group's guidelines emphasize a science- and risk-based approach to supplier qualification and ingredient testing. Those developing the guidelines trust that science- and risk-based principles will also be the foundation for future guidance and rulemaking related to the Food Safety Modernization Act ("the FSMA" or "the Act"). Several FDA regulated industries, including the dietary supplement industry, have been developing voluntary guidelines for supplier qualification for their respective industries. FDA is requested to consider the documents developed by the Working Group as a basis for the important work that will be done throughout the implementation of the FSMA.

## I. Section 301 Foreign Supplier Verification Program (FSVP)

Under Section 301 of the FSMA, the Foreign Supplier Verification Program (FSVP) requires importers to conduct risk-based foreign supplier verification activities to verify imported food is not adulterated or misbranded, and is produced according to FDA requirements outlined in Sections 418 or 419 of the Act, as appropriate. Three Working Group initiatives (two completed, one in progress) may be valuable tools to help dietary supplement companies as they develop risk-based programs to verify supplier activities.

### 1. SIDI™ Protocol (see Appendix A)

The SIDI™ Protocol was developed as a voluntary guideline to standardize exchange of relevant and required information between dietary component suppliers and dietary supplement manufacturers. The SIDI™ Protocol[9] outlines the type and scope of information that a component supplier typically needs to provide to dietary supplement manufacturers and is freely available to the general public[10]. It is not intended to replace corporate audits of suppliers. The SIDI™ Protocol contains two sections (product information and site quality overview) that identify the minimum type and scope of information that should be addressed in the SIDI™ document developed by the component supplier. Important elements of supplier verification are suggested for inclusion within the product information section which

[7] FDA Food Safety Modernization Act: Title III – A New Paradigm for Importers; Public Meeting. Accessed March 24, 2011, from http://edocket.access.gpo.gov/2011/pdf/2011-5942.pdf.
[8] Hamburg, MA. Commissioner of Food and Drugs. Letter to Dietary Supplement Manufacturers, Dec 15, 2010. Available at: http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/UCM236985.pdf
[9] Developed based on the Excipient Information Protocol (EIP) developed by the International Pharmaceutical Excipients Council (IPEC)
[10] SIDI™ documents are available at www.crnusa.org/SIDI and www.chpa-info.org/Web/SIDI/index.html

addresses regulatory information: Food Additive, Generally Recognized as Safe (GRAS), and New Dietary Ingredient (NDI) status; allergen information; current Good Manufacturing Practice (cGMP) status. There is also an extensive glossary of terms and list of regulatory internet links that can serve as a resource of regulatory information for use in the supplier qualification process.

2. Certificate of Analysis Guideline for Dietary Supplement Components (see Appendix B)

   The Certificate of Analysis (CofA) Guideline for Dietary Supplement Components[11] was developed as a voluntary guideline for the preparation by suppliers and appropriate use by their customers of a Certificate of Analysis for dietary supplement components. The goal is to standardize the content and format of CofAs for dietary supplement components, and to clearly define the roles and responsibilities for component suppliers, distributors, dietary supplement manufacturers and other users who need to meet the requirements of 21 CFR 111.

3. Voluntary Supplier Qualification Guideline

   This initiative, currently in progress, involves the development of a voluntary Supplier Qualification Guideline that will assist manufacturers of dietary supplements and users of dietary supplement components in meeting the requirements for supplier qualification as outlined in 21 CFR Part 111.75. The Guideline will incorporate concepts and recommendations, based on the basic principles of risk management as described by the International Conference on Harmonization[12], that address the most critical aspects of component supplier qualification. Once available, this voluntary Guideline, in conjunction with other guidelines and tools, could be used in the development of a comprehensive evaluation program for supplier qualification.

We request that FDA considers these industry-initiated tools as resources as the Agency develops regulations and future guidance on foreign supplier verification. Furthermore, we suggest that the Agency consider harmonizing expectations and requirements for domestic and foreign suppliers to the extent possible.

## II. Section 106 Protection Against Intentional Adulteration

Section 106 of the Act directs the Health and Human Services (HHS) Secretary to "determine the types of science-based strategies and measures that are necessary to protect against the intentional adulteration of food."[13] Comprehensive raw material testing is one method to identify intentional adulteration. However, testing alone cannot assure the quality of incoming components. A firm cannot set a

[11] The Certificate of Analysis Guideline for Dietary Supplement Components is available at www.crnusa.org/SIDI and www.chpa-info.org/Web/SIDI/index.html

[12] ICH Q9 Quality Risk Management Guideline, International Conference on Harmonization, November 2005. Accessed at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm128053.pdf on April 8, 2011.

specification and test for an adulterant that it does not know exists or for which no scientifically validated test method is available. Overly prescriptive testing requirements come with a substantial cost burden and do not account for unknown adulterants. Members of the Working Group believe that sound supplier qualification combined with appropriate testing of incoming components will assist in protecting the U.S. food supply.

## III. Section 303 Authority to Require Import Certifications for Food

Section 303 of the FSMA states that the determination that an article of food is required to have a certification shall be based on a number of factors, including known safety risks associated with the food and "…a finding supported by risk-based, scientific evidence…that the food safety programs, systems, and standards in the country, territory, or region of origin of the food are inadequate to ensure that the article of food is as safe as a similar article of food manufactured, processed, packed, or held in the United States…."[13] As of June 25, 2010, all manufacturers of dietary supplement products marketed in the U.S. have been subject to the dietary supplement cGMP which outlines the compliance responsibilities for dietary supplement manufacturers. Additionally, firms are subject to FDA inspection to assure compliance with existing U.S. statutes and regulations. Therefore, members of the Working Group hope that FDA recognizes that dietary supplements are subject to cGMP regulations when determining which articles of food must be certified and will consider exempting dietary supplements from this requirement.

## IV. Section 307 Accreditation of Third-Party Auditors

The FSMA requires the HHS Secretary to establish a system for recognition of accreditation bodies to accredit third-party auditors within two years of enactment. Foreign governments and other third parties are eligible to be accredited as third-party auditors under the Act. One of the long-range goals of the Working Group is to develop a shared audit system for dietary component suppliers. The audit process is time, labor, and resource intensive for both manufacturers and suppliers. An FDA-recognized third-party auditor accreditation system would allow the industry to maximize the use of these resources while ensuring a robust, risk-based audit of ingredient suppliers.

## Conclusions

Members of the Working Group appreciate the opportunity to provide input to the FDA on the Food Safety Modernization Act: Title III – A New Paradigm for Importers. The Working Group initiatives are directly in line with the principles intended by the Act. We feel that the science- and risk-based principles that underpin the Working Group voluntary guidelines should serve as a basis for guidelines and regulations that arise from the FSMA. In addition, given that dietary supplements are addressed in other regulations and legislation, the Working Group encourages FDA to exempt dietary supplements

[13] Public Law 111–353. The FDA Food Safety Modernization Act. Accessed from http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf on April 4, 2011.

from import certification. We support the Agency's effort to establish accredited third party auditors, which will further the Working Group's efforts to ensure supply chain integrity. The Working Group is happy to answer questions and to collaborate with the Agency as appropriate.

Sincerely,

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Enclosures (2)