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RE: Docket No. 96N-0417

August 7, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane, rm. 1061
Rockville, MD 20852

Dear Sir or Madam:

The National Nutritional Food Association (NNFA) and NSF International (NSF) jointly submit the following comments on the proposed rules for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements, Docket No. 96N-0417, ("proposed rule"). NNFA and NSF will also submit separate comment letters addressing issues related to the proposed rule. Both NNFA and NSF fully support current good manufacturing practices (cGMPs) for dietary ingredients and dietary supplements. Moreover, we strongly believe that FDA should consider relying on third-party conformity assessment organizations to assist in the implementation of the final GMP regulations.

As background information, both NNFA and NSF offer third party conformity assessment services to the Dietary Supplements industry. NNFA offers GMP certification services and NSF offers GMP registration services and product testing certification services based on the requirements of the American National Standard NSF/ANSI 173 (2003) – *Dietary Supplements*. These third party services include initial auditing of the facilities to verify compliance with the GMP requirements. If products are being considered for NSF Certification, product is selected during the audit and tested for: ingredient identification, quantity of active ingredient(s), and verification the product does not contain unacceptable quantities of contaminants. The GMP audit programs and product certification programs require ongoing surveillance audits and product testing to ensure continued compliance by the manufacturer.

The use of third party conformity assessment organizations by federal agencies is supported through legislation. In February 1996, The National Technology Transfer and Advancement Act (NTTA) of 1995 was enacted by Congress. The intent behind NTTA is to eliminate "unnecessary duplication and complexity in the development and promulgation of conformity assessment requirements and measures." Using the results of private sector conformity assessment activities as offered by NNFA and NSF is a viable method for FDA to comply with the NTTA.

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Under the NTTA, the National Institute of Standards and Technology (NIST) is directed to coordinate conformity assessment activities of federal, state and local entities with private sector technical standards activities and conformity assessment activities with the goal of eliminating any unnecessary duplication of conformity assessment activities. To this end, NIST issued the *Guidance on Federal Conformity Assessment Activities* (15 CFR Part 287, Docket No. 981222315-0219-02). The Office of Management and Budget (OMB) Circular A-119 directed the Secretary of Commerce to issue such guidance to the agencies to ensure effective coordination of federal conformity assessment activities. The Guidance document states, "Each agency is responsible for coordinating its conformity assessment activities with those of other appropriate government agencies and with those of the private sector to make more productive use of the increasingly limited Federal resources available for the conduct of conformity assessment activities and to reduce unnecessary duplication."

There are many examples of federal agencies embracing the intent of NTTA leading to successful and efficient conformity assessment programs utilizing the resources of third party providers. Below is a brief description of two programs:

In the late 1980's, the U.S. Environmental Protection Agency (USEPA) put out a competitive bid to develop voluntary third party consensus standards and a certification program for all direct and indirect drinking water additives. A consortium led by NSF was awarded the contract. As a result, NSF/ANSI 60: *Drinking water treatment chemicals – Health effects* and NSF/ANSI 61: *Drinking water system components – Health effects* were developed and NSF, as well as other third party product certifiers, provide independent testing and certification of drinking water chemicals and components against the two Standards. Based on the success of the program developed by NSF the USEPA terminated its Additives Advisory Program and now fully depends on third party programs to provide the services. Today, federal, state and local agencies responsible for providing safe drinking water look for the NSF certification mark on products being used in the treatment and transportation of drinking water as assurance products meet minimum public health requirements.

The Occupational Safety and Health Administration (OSHA) administers a program under the Office of Technical Programs and Coordination Activities whereby testing laboratories are recognized as qualified to test equipment used in the workplace. Laboratories found to comply with the requirements set forth by OSHA are listed on the OSHA website as Nationally Recognized Testing Laboratories (NRTLs). OSHA only accepts equipment or products approved by one of the listed NRTLs. OSHA field inspectors look for a NRTL certification mark on equipment to have assurance that the equipment has been found to meet the appropriate safety requirements. By utilizing third party private sector certification bodies, OSHA manages their resources efficiently while ensuring a safe workplace environment. Additional information on the OSHA program can be found at the following web address: http://www.osha.gov/dts/otpca/nrtl/.

In general, federal agencies that have taken advantage of incorporating the use of third party private sector entities into their compliance monitoring systems have embraced international standards to define the minimum requirements for certification bodies, testing laboratories, and auditing groups. The relevant standards available include the following:

- ISO/IEC Guide 65, *General requirements for bodies operating product certification systems.*
- ISO/IEC 17025, *General requirements for the competence of calibration and testing laboratories.*
- ISO/IEC Guide 39, *General requirements for the acceptance of inspection bodies.*

The international standards referenced above set minimum criteria including, but not limited to: personnel qualification, systems to avoid conflict-of-interest issues, public notification of certified products, enforcement procedures, and complaint handling procedures.

In the United States, federal agencies typically determine the competence of a third party to perform audits to confirm compliance with federal programs in two ways. The agency may decide to directly recognize the competence of third party bodies as the result of inspections conducted by the agency. Another approach, which provides less of a resource burden on the agency, is to rely on private sector or other government agency accreditation programs to accept conformity assessment bodies.

A compliance program to enforce dietary supplement cGMPs that includes the use of third party conformity assessment bodies will benefit stakeholders, including consumers, FDA and responsible members of the industry. The third party system can assist FDA and industry in assuring compliance and reduce the burden on FDA to implement the regulations in the following ways:

- They provide third party independent assurance that ingredient suppliers and supplement manufacturers meet minimum system and testing requirements.
- By allowing efficient utilization of existing resources by the FDA. For instance, responsible manufacturers and suppliers utilizing services from recognized third party providers may merit reduced monitoring by FDA. Agency resources are then available to focus on companies that are clearly operating outside of the law.

The use of third party conformity assessment services by federal agencies has a proven and successful track record and is encouraged through legislation. Both NNFA and NSF respectfully request FDA use third party systems in to implement and promote compliance with final cGMP rules. We both stand ready to work with the FDA in developing a system that can provide maximum benefits to all stakeholders while ensuring full compliance with the regulations and protection of the public health.

Sincerely,

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