



U.S. Pharmacopeia
The Standard of Quality™

June 22, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Subject: Comments of USP on “FDA Food Safety Modernization Act:
Focus on Inspections and Compliance”
Docket No. FDA-2011-N-0366

Dear Sir/Madam:

This letter is in response to the recent public meeting held by the Food and Drug Administration (FDA) on June 9, 2011 concerning implementation of Food Safety Modernization Act (FSMA) provisions related to inspections and compliance.

Under “Frequency and Targeting of Facility Inspections,” FDA seeks data sources or criteria that it could consider in determining when a food facility is “high risk.” This supports FDA’s recently-announced global strategy to allocate resources based on risk, including leveraging public and private third parties and industry. One consideration in developing a **risk-based priority schedule for inspections** is facility participation in a **voluntary third-party verification/certification program**.

In meetings with FDA, the United States Pharmacopeial Convention (USP) has conveyed that our third party conformity assessment (verification) programs for dietary supplements and dietary supplement ingredients (<http://www.usp.org/USPVerified/>), and similarly directed programs, could serve as a helpful model to FDA in reaching FSMA objectives related to foreign supplier certification and verification requirements—strengthening the food supply chain in an era of scarce resources and increased workload. USP’s current verification programs could be readily extended to all foods, including food additives/ingredients, medical foods, processed foods, final foods, and functional foods.

As a neutral, expert, scientific standards-setting organization, USP is able to conduct a rigorous voluntary third-party assessment program that offers greater independence than those programs operated directly by first or second parties (suppliers or purchasers), and it is for this reason that manufacturers and consumers find our third-party programs a trusted indicator of quality. USP also goes to considerable lengths to separate its standard-setting activities from its conformity assessment activities, to preserve the integrity and independence of both sets of activities.

Under its Verification Program for Dietary Supplements (the Verification Program), USP evaluates and verifies the quality of finished dietary supplements according to stringent standards for product purity, authenticity, accuracy of ingredient labeling, and proper manufacturing practices. Products that meet the program’s rigorous requirements are awarded the right to use the **USP Verified Mark** on their labels. The program’s components are further outlined in **Attachment 1** (see additionally the Participant Manual available at <http://www.usp.org/pdf/EN/USPVerified/DSVPMannual.pdf>).

Headquarters

12601 Twinbrook Parkway
Rockville, Maryland 20852
+1-301-881-0666

Europe/Middle East/Africa

Münchensteinerstrasse 41
CH-4052 Basel, Switzerland
+41 (0)61 316 30 10

USP-India Private Limited

ICICI Knowledge Park
Genome Valley
Labs 7-10, Phase III
Turkapally, Shameerpet
Ranga Reddy District
Hyderabad 500 078, A.P., India
+91-40-2348-0088

USP-China

Building 11
Lane 67 Libing Road
Zhangjiang Hi-Tech Park
Shanghai, 201203, China
+86-21-51370600

USP-Brazil

Avenida Ceci, 1600 - Tamboré
Barueri/SP, Brazil
06460-120
+55-11-3245-6400

In addition to our program for finished dietary supplements, we also have verification programs for dietary supplement ingredients and pharmaceutical ingredients, including drug substances and excipients. We find it helpful and encouraging that FDA will look to partnerships to facilitate the implementation of FSMA. Such collaborations are consistent with FDA's objective to increase its reliance on third party inspections and FDA's desire to work more closely with other countries in leveraging their food safety efforts. We also note the third-party activities present in FDA's FY '12 budget. We offer USP's resources and expertise in any way that would be helpful.

Please let us know if we can be of further assistance. You can contact Director of Government Affairs Ben Firschein on my staff at baf@usp.org, (301) 816-8235.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Williams", written in a cursive style.

Roger L. Williams, M.D.
Chief Executive Officer

Attachment

Attachment 1: USP Dietary Supplement Verification Program Components



To determine whether a dietary supplement is entitled to display the **USP Verified Mark** on its label, the USP Verification Program for Dietary Supplements (the Verification Program), <http://www.usp.org/USPVerified/dietarySupplements/>, conducts (1) a thorough and rigorous audit of the manufacturing facility to ensure compliance with USP and FDA standards for Good Manufacturing Practices (GMPs); (2) a comprehensive, scientific review of the product's manufacturing and quality control processes and documentation to ensure that the product will be manufactured with consistent quality from batch to batch; and (3) extensive laboratory testing of the product to verify conformity with the product's specifications and labeling.

First, the manufacturing facilities are inspected for compliance with USP and FDA standards for Good Manufacturing Practices (GMPs). The GMP inspection is detailed and is conducted based on a quality systems approach. The six quality systems covered include quality management, facilities and equipment, materials control, production processes, packaging and labeling, and laboratory controls. GMP compliance generally assures that the manufacturing facility is subject to careful oversight and control and that the systems are functioning properly, helping to prevent contamination or adulteration of the products.

Second, the manufacturer's product documentation of its quality control and manufacturing procedures is reviewed. This review examines the product's compliance with applicable specifications for dietary ingredients, excipients, packaging and labeling materials, and the finished product. The review also examines the testing method(s) and reference materials used by the manufacturer, to ensure that they are appropriate and accurate, and the product's stability data to ensure that the product will retain its quality throughout its marketed shelf life period. Manufacturing documentation is reviewed to verify that the master formula, manufacturing process directions, packaging instructions, product labeling, and indication of quality assurance final release approval are acceptable.

Third, the supplements are tested against USP established standards for identification, strength, purity and performance characteristics, *e.g.*, dissolution and disintegration. This testing is performed by USP's laboratories and other third-party laboratories with demonstrated expertise in evaluating the complex composition of vitamin, mineral, and botanical compounds.

If a product meets the Verification Program criteria, the manufacturer is entitled to use the USP Verified Mark on the product's labeling. Thereafter, USP periodically will test randomly selected off-the-shelf lots of the product to ensure that they continue to meet the program's strict standards. The dietary supplement manufacturing sites will be audited for GMP compliance on an annual basis, with a full audit every three years, and surveillance audits during the intervening years.