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Review Comment

Docket Information**Docket ID** FDA-2008-D-0381**Long Title** Draft Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds; Availability**Document Information****Document ID** FDA-2008-D-0381-0001**Document Title** Draft Guidance for Industry on Voluntary Third-Party Certification Programs for Foods and Feeds; Availability**Submitter Information****Submitter Category** Other Organizations - E0003**Country** United States**Organization Name** United States Pharmacopeial Convention (USP)**Third Party****Comments**

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) thanks the US Food and Drug Administration (FDA) for the opportunity to comment on the FDA's draft Guidance for Industry: Voluntary Third-Party Certification Programs for Foods and Feeds [Note 1].

We are supportive of this effort, and pleased that the draft guidance implicitly recognizes the role and importance of standards and other safeguards in helping to ensure safe imports. We believe that third-party certification programs, along with Good Manufacturing Practices (GMPs) and other measures, could play an important role in promoting food security and safety.

We note that the draft guidance mirrors in some key respects the verification programs developed and launched by USP for dietary supplements, dietary supplement ingredients, drug substances, and excipients [Note 2]. Many elements of USP's current verification programs -- GMP audit, document review, testing for conformity assessments, certification, surveillance testing, and decertification --- are attributes of third party certification programs sought by the FDA in the draft guidance. Thus, USP's programs may serve as helpful examples to the FDA in its efforts to encourage certification efforts in the area of foods and feeds.

In USP's programs, GMP audits play an important role, since quality cannot be assured solely by testing. For example, in USP's programs, inspection reports identify major and minor deficiencies noted in the manufacturing process and until corrective actions for major deficiencies are implemented, certification letters are withheld. One of the important requirements of these programs relates to change control, and mandates that USP be notified of all major and moderate changes (as defined in USP manuals), prior to implementation. This helps ensure consistency in the quality and safety of the products/ingredients certified.

We also strongly believe in the role and importance of public standards in advancing verification programs and other food protection efforts. Measures of quality, purity, and identity for preservatives, antioxidants, colors, and other substances used as components of food can provide an established standard to which to verify and test food and food ingredients, making available to all- industry, consumers, and government -- an accepted measure, thereby creating public

confidence in products and their ingredients, and promoting the movement of such goods in international commerce.

Public standards are established to protect the public health, thwarting intentional adulteration and counterfeiting, by allowing rapid updating of monographs to address new threats. This was recently demonstrated with the recent USP-FDA cooperation on heparin and glycerin monographs, and is potentially equally as valuable in the area of foods and feeds. We would therefore be appreciative of an opportunity to work with FDA to augment standards-setting efforts in the foods area.

While USP is best known for setting quality standards for drugs, drug products, dietary supplements, excipients and biologicals in the USP-NF, it also now sets standards for food ingredients, using the same open and participatory science-based processes used to establish its drug standards. The food ingredient standards are published in the Food Chemicals Codex (FCC), which USP recently acquired from the Institute of Medicine (IOM) and has since updated and republished in its 6th edition.

At present, a limited number of FCC standards are incorporated into specific FDA regulations approving particular food additives, but unlike the drug standards in the USP-NF, FCC food ingredient standards do not have broad legal recognition in the United States. Although the Secretary has the current authority under the Food, Drug, and Cosmetic Act to set food ingredient standards, and does so as evidenced in 21 CFR Parts 172-189, many of the established food ingredient criteria are now outdated or lacking in the necessary detail to provide adequate guidance to the food industry or confidence in the consumer. We would therefore request that FDA work to find ways to update and enhance recognition of standards in this area, and as noted, we think that would also benefit certification programs.

We thank FDA again for the opportunity to comment. We would be very pleased to share with you our experiences and expertise in developing and conducting verification programs during the past seven years, our more recent experience with FCC, and our related expertise and partnership with FDA in advancing public standards over the last century, and to discuss how this knowledge might be helpful in developing verification programs for foods and feeds.

Sincerely,

The United States Pharmacopeial Convention

For additional information, please contact:

V. Srini Srinivasan, Ph.D.
Vice President, Verification Programs
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852
P (301) 816-8334
VS@USP.org

Ben A. Firschein, J.D.
Director, Government Affairs
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852
P (301) 816-8235
F (301) 998-6798
baf@usp.org

Notes:

[1] <http://www.fda.gov/oc/guidance/thirdpartycert.html>.

[2] See <http://www.usp.org/USPVerified/>. USP verification programs relating to drug substances, excipients, and dietary ingredients are global in nature, and manufacturers from China, India, Canada, Argentina, Peru, and other countries are taking part in these programs. FDA's draft guidance notes that "recommendation 2 of the [President's] Action Plan is to 'verify compliance of foreign producers with U.S. safety and security standards through certification,'" and that the Food Protection Plan "emphasizes certification as a way to help verify the safety of [food] products." (See, page 4). Additionally the draft guidance provides that "inspectors should determine if an establishment has an effective, documented program to verify product safety using scientifically sound methods." (See, page 12).

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