U.S. Pharmacopeia
The Standard of Quality℠

April 19, 2011

Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane
Room1061
Rockville, MD 20852

Subject: Comments of USP on “FDA Food Safety Modernization Act: Title III—A New Paradigm for Importers; Request for Comments” Docket Nos. FDA–2011–N–0134, FDA–2011–N–0143, FDA–2011–N–0144, FDA–2011–N–0145, and FDA–2011–N–0146

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the recent hearing held by the United States Food and Drug Administration (FDA) on the implementation of the Food Safety Modernization Act (FSMA). 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 national food safety efforts. We also note the third-party certification activities present in FDA's FY '11 budget and supported by the FSMA. We offer USP’s resources and expertise in any way that would be helpful to accomplish FSMA goals.

We have had a number of positive interactions with FDA regarding standards for the authenticity, quality, and purity of food ingredients and dietary supplements. USP was also encouraged by Commissioner Hamburg's recent mention http://www.fda.gov/NewsEvents/Speeches/ucm209514.htm of the value of USP's food ingredient standards—including our international activities in that area—and she expressed FDA's desire to continue to work closely with stakeholders to find ways to combat adulteration.

In meetings with FDA staff we have conveyed that USP’s food ingredient standards as well as its dietary supplement standards (and related verification programs for dietary supplements and dietary supplement ingredients, http://www.usp.org/USPVerified/), are used throughout the world to help ensure the quality of foods and dietary supplements. Our *Dietary Supplements Compendium* is legally binding for manufacturers who represent their supplements as being USP-compliant, and our *Food Chemicals Codex* is recognized in over 200 federal food regulations and in countries including Canada, New Zealand, Australia, and Israel.

Standards development is facilitated by our working relationship with FDA. FDA liaisons participate in USP Expert Committee meetings, and FDA also joins in USP workshops on various topics including adulteration. FDA standards-setting committees have links with USP, and USP collaborates with each FDA center.

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While we don't have a verification program for food ingredients, the above programs could provide assistance and serve as a model to FDA in reaching FSMA third-party certification objectives, strengthening the food chain in an era of scarce resources and increased workload for the agency. Our programs can be helpful in aiding FDA in its efforts to protect consumers and ensure the integrity of manufacturers' products, as the presence of adulterants compromises not only the quality but also the safety of the adulterated product.

Quality and safety are intertwined: if quality is compromised, then safety is potentially compromised as well. And more dramatically, if and when adulteration occurs, the affected product is modified in a way that is unknown to all other parties in the supply chain and to regulators. As a consequence, any adulteration creates an incalculable risk to all parties in the food supply chain and ultimately to the health and safety of the consumer. The hazards of adulterated foods range from a significant health hazard such as through the illegal presence of carcinogenic Sudan Red Dyes in chili powder or toxic lead salts in paprika powder, to in the very least an economic defrauding of the consumer such as through the presence of undeclared defatted paprika powder. Compendial standards (and associated chemical reference materials) and voluntary verification programs are efficient and effective resources to determine the quality, purity and authenticity of food ingredients and combat adulteration of ingredients.

USP also offers international resources that could be useful in leveraging FSMA and other quality efforts. Aligning closely with our facilities in China, India, and Brazil—as well as our headquarters in Rockville and office in Switzerland, USP has established new relationships with FDA's Office of International Programs staff in headquarters as well as in China, India, Europe, and Latin America and the Caribbean. In addition, USP is already assisting FDA in its international activities in various areas, including introductions to key industry, government contacts, and invitations to events – e.g., USP-hosted/sponsored technical meetings abroad, annual scientific and standards meetings, sharing information about medicine and food issues, and hosting visits by foreign drug agency officials. USP also offers professional education programs, http://www.usp.org/products/pe.html, to further the cause of making food, drug, and dietary supplement ingredients safer.

We also invite FDA staff to participate in a workshop we will have in Rockville on November 16-17 on adulteration of food ingredients and dietary supplements. We would be pleased to provide additional information.

Thank you for the opportunity to submit this comment. Please let us know if we can be of further assistance. You can contact Ben Firschein on my staff at baf@usp.org, (301) 816-8235.

Sincerely,

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