U.S. Pharmacopeia
The Standard of Quality℠

July 19, 2012

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
Submitted electronically to the docket.

Subject: Comments of USP on FDA's International Capacity Building Plan under the Food Safety Modernization Act (FSMA), Docket No. FDA-2012-N-0437

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the public meeting held by the Food and Drug Administration (FDA) on June 19 to seek input on FDA's international capacity building plan under the FSMA. As a global organization that sets legally recognized quality standards for food ingredients and engages in other public health activities around the world, our main message is that collaboration is important, USP's verification and other programs can assist FDA with its implementation of FSMA, quality standards play a role in safety, and food should explicitly include food ingredients.

I. General Comments

A. Importance of Collaboration

FDA's draft plan (and FSMA itself) contemplates FDA's collaboration with others; this is also consistent with FDA's global strategy and recent FDA recommendations by the Institute of Medicine. There are specific areas where USP can be a resource and collaborate with FDA through our standards-setting and other activities:

1. FSMA requires food facilities to evaluate hazards and implement risk-based controls. Hazards include **naturally occurring or unintentionally or intentionally added**, including biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and color additives (FSMA Sec. 103).

2. The law requires the Secretary (FDA) to create performance standards and guidance to help prevent significant foodborne contaminants and also develop regulations to deter **adulteration (Sec. 104).**

3. The law requires manufacturers to identify food at **highest risk of adulteration** and take steps to mitigate that risk. **(Sec. 106).**

4. The law creates a foreign supplier **verification** program **(Sec. 301)** and a voluntary qualified importer program **(Sec. 302).**

5. The Act provides for **training** of domestic food safety officials **(Sec. 209)** as well as building the **capacity** of foreign governments **(Sec. 305).**

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Ways USP can add value include:

1. USP's compendial (written) standards and associated chemical, botanical, and biological physical reference materials and voluntary verification programs can be efficient and effective resources to determine the quality, purity and authenticity of food ingredients and combat adulteration of ingredients. USP's food ingredient standards (http://www.usp.org/food-ingredients) 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 supplement standards are legally binding for manufacturers who represent their supplements as being *USP*-compliant, and our *Food Chemicals Codex* (*FCC*) is recognized in over 200 federal food regulations and in countries including Canada, New Zealand, Australia, and Israel. Argentina, Brazil, Uruguay and Paraguay require authorized food additives to comply with purity requirements established by FAO/WHO or *FCC*. Additionally, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), an international scientific body that evaluates and assesses the safety of food additives for the Codex Alimentarius Commission, has used certain *FCC* specifications to develop its standards.

2. We have applied our verification programs to dietary supplements, dietary ingredients, and excipients, and these same principles can be advanced by the Agency or third parties with respect to food ingredients (for a detailed description of how the programs work see: http://www.usp.org/sites/default/files/usp_pdf/EN/USPVerified/divpparticipantguidelines.pdf). USP's verification programs can 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. They can aid 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.

3. USP's development of standards for foods, dietary supplements, dietary ingredients, excipients and drugs (substances and products) is facilitated by our close working relationship with FDA, which also helps ensure alignment between USP and 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. We are working with FDA on scientific issues relating to the identification and detection of adulterants such as melamine.

4. 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.

5. USP has developed a free food fraud database, www.foodfraud.org that could be used in combination with other resources by FDA and industry to assess food ingredients at risk of adulteration. We have been working closely with industry and others on this project.

6. USP also offers pharmacopeial education programs, http://www.usp.org/products/pe.html, which help teach others how to perform important quality control tests; suitable programs could further the cause of making food safer.

7. We are collaborating in standards-development work with governments around the world, including a Memorandum of Understanding (MOU) with the National Institute of Nutrition and Food Safety in China on translation of *FCC* standards, a joint workshop, and a planned food adulteration workshop in November; and MOUs and expert panels in India, including on dietary supplements. See: http://www.usp.org/around-world/regional-activities .

8. We offer capacity-building for drug quality through our USAID funded program on Promoting the Quality of Medicines (PQM), http://www.usp.org/global-health-impact-programs/promoting-quality-medicines-pqmusaid; a Technical Assistance Program (TAP), http://www.usp.org/global-health-impact-programs/technical-assistance-program-tap; and educational programs through a proposed Center for Pharmaceutical Advancement and Training (CePAT), http://www.usp.org/global-health-impact-programs/center-pharmaceutical-advancement-and-training-cepat. These activities could possibly be extended to foods.

B. Quality and Safety Both Matter

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, or melamine in milk protein powder, to in the very least an economic defrauding of the consumer such as through the presence of undeclared defatted paprika powder. USP standards help to establish the identity and purity of a product (i.e., that it is what it is purported to be and does not have impurities beyond a certain level).

Quality and safety are intertwined: if quality is compromised, then safety is potentially compromised as well. 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. Even something as apparently innocuous as "watering down" a food product (e.g. milk) can be hazardous or even deadly if water is contaminated with bacteria or other hazards, see, e.g., http://insights.ifpri.info/files/2012/03/dairy_cow_infographic.pdf.

II. Specific Comments on FDA's Document

Element 1: Recommendations for bilateral and multilateral arrangements and agreements, including provisions to provide for responsibility of exporting countries to ensure the safety of food. We recommend this element include a reference to food ingredients.

Under FDA recommendations ("FDA should seek opportunities with exporting countries and with other federal government agencies that optimize FDA's ability to leverage resources, rely on the findings of other government entities, and support joint capacity-building activities.") We recommend this include other parties, not just exporting countries and federal government agencies.

Element 2: Provisions for secure electronic data sharing. USP works closely with FDA and stakeholders in the development of standards while adhering to strict policies related to confidentiality and conflict of interest, (see, e.g., http://www.usp.org/about-usp/leadership/policies-rules/rules-procedures-2010-2015-council-experts/expert-panels). Where entities have in place such procedures, FDA should consider appropriate ways to share data necessary for standards development while also respecting intellectual property protections.

Element 3: Provisions for mutual recognition of inspection reports. We recommend that where third party certification/verification programs have proven effective in establishing quality and safety, such programs also be taken into consideration in deciding whether there is confidence in a product or regulatory regime.

Element 4: Training of foreign governments and food producers on United States requirements for safe food.

We recommend this element include specific reference to food ingredients, including risk of adulteration, and that it include guidance that FDA work with exporting countries, other federal government agencies, and other parties to facilitate FDA's goals.

The topic of intentional adulteration should be incorporated into webinars and other FSMA training domestically and abroad (as it is starting to be by industry and others).

Under the questions section, the Agency asks "what are the best ways to ensure that developing countries are engaged with any training efforts?" USP recommends the following guidance be added:

1) The impact of these efforts should be monitored and evaluated, so the success of these initiatives can be assessed.
2) A baseline of these initiatives needs to be established so needs by the different developing countries can be evaluated.
3) FDA should be encouraged to investigate methodologies that measure these initiatives.

Element 5: Recommendations on whether and how to harmonize requirements under the Codex Alimentarius.

While promoting harmonization with Codex is extremely important, this is not always feasible as standards for certain food ingredients do not exist and thus cannot be enforced. Moreover, some analytical methods suggested for the identification of materials are no longer used by industry and thus need to be reassessed. Moreover, the long time Codex requires to develop of standards is inconsistent with the level of innovation industry-wide, so engagement with other science-based standards-setting organizations (e.g. USP) and standards (e.g. *FCC*) capable to set industry standards should be considered and, where appropriate, listed.

Element 6: Provisions for the multilateral acceptance of laboratory methods and testing and detection techniques.

Screening for adulterants should also be mentioned.

We recommend the language be modified to state that FDA should partner with training institutions and domestic and international laboratory networks and other parties to conduct outreach and education.

Evidence Based Decision Making

We recommend that FDA's capacity-building plan should focus on preventing unsafe food and food ingredients from entering the U.S. market.

Establishing Partnerships

We recommend language state that FDA should seek greater coordination with other all global food/food ingredient safety actors in pursuing global and regional food safety capacity-building efforts.

Designed for Effectiveness

Under Recommendations:

We recommend this state that FDA should develop strategic results frameworks for partner countries and high-risk commodities with the aim of preventing food/food ingredient safety problems in the foreign food supply chain.

In summary, there are many ways USP and others could offer their assistance and we hope the Agency will be able to leverage those opportunities. Food ingredients are sometimes overlooked in everyday discussion, but they are a substantial component of the food supply. We should be especially vigilant in protecting the public in this area—as incidents such as melamine have demonstrated. Quality standards and verification programs can help, and we stand ready to offer our expertise.

Thank you for the opportunity to share these comments. Please let us know if we can be of further assistance. Questions should be directed to Ben Firschein, USP's Director of Government Affairs and Policy, at baf@usp.org, (301) 816-8235.

Sincerely,

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