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February 4, 2013

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

Subject: Comments of USP on "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food",
Docket No. FDA-2011-N-0920

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates the opportunity to comment on the above-captioned proposed rule related to implementation of the Food Safety Modernization Act (FSMA)—preventive controls. While the Food and Drug Administration (FDA) notes it intends to address intentional adulteration (including deliberate acts of terror) in a future rule, FDA seeks comment on *when economically motivated adulteration (EMA) (e.g. melamine) can be considered reasonably likely to occur; and should it therefore be covered by FDA in the current rulemaking.* Our comments are limited to that inquiry.

It is USP's position that:

- EMA and other types of adulteration are a well-documented risk.
- Historical data can help assess risk of adulteration.
- Appropriate standards and practices (testing, etc.) can be incorporated into a food safety plan and also enable the verification of ingredients.
- Adulteration—not limited to EMA—should be addressed in the final rule.

1. To Address Risk of Adulteration, History Provides a Starting Point

USP has a **free food fraud database**, <http://www.foodfraud.org/>, that can be useful for assessing risk of fraud, counterfeiting, or EMA. The database contains information on which foods have historically been reported adulterated and with what adulterant. Beyond listing ingredients subjected to food fraud, the database (when used together with other available information) provides a baseline understanding of susceptibility to fraud by offering a library of detection methods for adulterants as reported in peer-reviewed scientific journals. **This could be a helpful or recommended resource for industry and consumers.**

2. A Prerequisite to Risk Assessment is Knowledge of Ingredients

When adulteration occurs, product identity is modified in an unknown way; effects on public health may also be unknown (and possibly underestimated). Robust specifications, such as those in the *Food Chemicals Codex (FCC)*, <http://www.usp.org/food-ingredients/food-chemicals-codex>, a compendium of food ingredient standards—or similar standards—are valuable as a starting point to determine the identity and purity of a food ingredient and help prevent adulteration.

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

Europe/Middle East/Africa
Münchensteinerstrasse 41
CH-4052 Basel, Switzerland
+41 (0)61 316 30 10

USP-India Private Limited
ICICI Knowledge Park
Turkapally Village, Genome Valley
Shameerpet, Ranga Reddy District
Hyderabad 500 078, A.P., India
+91 40-4448-8888

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

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

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FCC is recognized in over 200 FDA regulations and abroad—including in Canada, New Zealand, Australia, Israel, and South America's Mercosur countries. *FCC* monographs (written standards) and associated reference materials (chemical "yardsticks") ensure that standards are met and test methods are performed appropriately. **This is an important component of any food safety plan and supplier verification program.** While USP does not now have a food ingredient verification program, USP's voluntary verification programs for pharmaceutical ingredients, dietary supplements, and ingredients used in dietary supplements (www.USP.org/usp-verification-services) are a proven approach and can serve as a model to assure quality for suppliers and purchasers.

3. Third Party Resources Can Help

FDA's global strategy (including for food) calls for leveraging the combined efforts of government, industry, and public-private partnerships. In this regard we offer USP's expertise in food ingredient standards and adulteration. We would welcome the opportunity to demonstrate the usefulness of *FCC* and the Food Fraud Database.

These resources would build on FDA's and USP's already-close working relationship in standards development for drugs, dietary supplements, and food ingredients. In addition to FDA's recognition of selected *FCC* food ingredient and food additive standards mentioned above, FDA liaisons presently 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, including the Center for Food Safety and Applied Nutrition (CFSAN).

Thank you for the opportunity to comment. Please let us know if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'R. Williams'.

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

Cc: Michael Roosevelt, Deputy Director, Office of Compliance, CFSAN