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VIA ELECTRONIC SUBMISSION

February 21, 2017

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

Re: Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food; Docket No. FDA-2016-D-2343
81 Fed. Reg. 57816 (August 24, 2016)

The United States Pharmacopeial Convention, Inc. (USP) appreciates this opportunity to submit comments on FDA's Draft Guidance on Hazard Analysis and Risk-Based Preventive Controls for Human Food (HARPC Draft Guidance). USP is committed to supporting FDA as it implements requirements of the FDA Food Safety Modernization Act (FSMA). In particular, we feel that our activities in the food fraud mitigation area can play a vital role in helping regulators and the food industry address hazards associated with economically motivated adulteration (EMA) or "food fraud," which is an important part of a robust HARPC compliance strategy.

In the following pages, we summarize USP's ongoing activities in the area of food fraud mitigation, highlighting resources currently available to interested stakeholders. We also discuss the utility of the *Food Chemicals Codex* (*FCC*) as a resource for establishing and maintaining the identity, purity, and quality of components in the food supply.

I. USP's Food Fraud Mitigation Tools Help Combat EMA in the Context of HARPC Compliance

As FDA indicates in the HARPC Draft Guidance, a "hazard" is "any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury."[1] FDA expressly states that this definition encompasses hazards "that may be intentionally added to a food for purposes of economic gain (i.e., economic adulteration)."[2] It is in this context that USP's Food Fraud Database and Food Fraud Mitigation Guidance can serve as useful tools to food industry stakeholders. Both resources were developed based on extensive input from USP's food ingredient expert volunteers and evaluated by food experts around the world. We were fortunate to have had FDA government liaisons participate in the Expert Panels that developed the Food Fraud Mitigation Guidance and the framework for identifying hazardous adulterants now implemented in the Food Fraud Database. Agency representatives provided invaluable feedback that helped us develop these resources, which we hope will help regulators, the food industry, and other stakeholders to combat food fraud and to improve the overall quality and safety of the global food supply.

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1 HARPC Draft Guidance, at page 13.
2 *Id.*

A. *Food Fraud Database*

We appreciate FDA's reference to the utility of USP's Food Fraud Database (FFD) in the HARPC Draft Guidance.[3] Since the original FFD launch, USP has worked to expand and enhance the database, improving its relevance and alignment with the preventive controls framework.

Launched in July 2016, FFD Version 2.0 (https://www.foodfraud.org/) is a continuously updated collection of thousands of food fraud-related records gathered from scientific literature, media publications, regulatory reports, judicial records, and trade associations from around the world. With over 6,200 records and growing, our goal is to maintain the largest and most current database of historical records of food fraud in existence. In its current iteration, the FFD is a subscription-based portal that provides a user-friendly way for interested parties to review, search, and analyze data related to food fraud incidents around the world. The FFD features records that include ingredients that were adulterated, the identity of the adulterant, the method used to detect the adulterant, and whether the adulterant is hazardous to human health. Users can identify trends and vulnerabilities specific to ingredients of interest and receive updates as new records are added to the database. From a regulatory compliance perspective, the FFD is now enhanced to generate EMA hazard identification reports that users may find beneficial in developing and implementing food safety plans under the HARPC requirements.

B. *Food Fraud Mitigation Guidance*

We also appreciate FDA's reference to USP's Food Fraud Mitigation Guidance (FFMG) in the HARPC Draft Guidance.[4] Published in 2015, the FFMG (http://www.usp.org/food/food-fraud-mitigation-guidance) is a free online resource that provides a comprehensive, practical approach to help food suppliers perform a food fraud vulnerability assessment on an ingredient-specific basis and to develop a customized mitigation plan.

It is our hope that these food fraud resources will be used more broadly by FDA, industry, and other stakeholders to enhance global food quality and safety.

II. The *FCC* Serves as a Resource to Enhance Food Ingredient Identity, Purity, and Quality

Originally published in 1966, the *Food Chemicals Codex* (*FCC*) is a compendium of food ingredient standards. Since assuming stewardship of the *FCC* in 2006, USP has worked to develop and update validated, peer-reviewed public standards, called "monographs," for food substances that include tests, procedures, and acceptance criteria to ensure the identity, purity, and quality of such products. We are grateful to have active and engaged government liaisons from FDA on the USP Food Ingredients Expert Committee, which works to develop *FCC* monographs. At present, the *FCC* contains monographs for more than 1,200 food substances. In conjunction with *FCC* monographs, USP also develops and supplies the industry with reference materials for food substances, as well as for related impurities and contaminants. These reference materials are highly characterized substances intended for use in conducting quality control tests and analytical procedures associated with specifications in established monographs.

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[3] *Id.*, at page 63.
[4] *Id.*, at page 78.

To date, FDA has issued more than 200 regulations for food substances that incorporate *FCC* specifications by reference. The *FCC* also is recognized by regulatory bodies around the world, including Canada, Australia, New Zealand, and Brazil. Even where not expressly recognized in the food regulatory framework, *FCC* monographs are widely used as a benchmark for "food grade" quality specifications in contractual agreements among food producers to ensure supply chain integrity.

In USP's view and experience, in-depth knowledge and understanding of food ingredient specifications can serve as a helpful prerequisite to developing a robust HARPC compliance plan. *FCC* monographs and their associated reference materials can help food ingredient suppliers ensure that quality standards are met and that test methods are performed appropriately.

We encourage FDA, industry, and other stakeholders to continue to collaborate with USP in our efforts to develop transparent, science-driven standards – such as those in the *FCC* – because they serve an important role in helping to secure the quality and safety of food ingredients in the global supply chain.

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We thank FDA for the opportunity to submit comments on the HARPC Draft Guidance, and we look forward to working collaboratively with the Agency and others in this area to ensure that USP can serve as a resource in enhancing the quality and safety of the food supply.

In particular, we would welcome the opportunity to meet with FDA food safety representatives to fully explore and expand upon our shared goals and to discuss opportunities where USP may offer resources and support to complement FDA's efforts in this area. We look forward to providing more detailed information on the food fraud mitigation tools discussed above – including an in-depth demonstration of the FFD – to the Agency at your convenience. Please feel free to contact Elizabeth Miller, Vice President, U.S. Public Policy and Regulatory Affairs, at ehm@usp.org; (240) 221-2064, with any questions or to schedule a meeting.

Sincerely,

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