October 9, 2018

Food and Drug Administration
Division of Dockets Management
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Attn: Docket No. FDA-2018-N-2381, FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy

Dear Sir/Madam,

The United States PharmacopeiaI Convention (USP) appreciates the opportunity to provide written comments in addition to the oral testimony we gave on July 26, 2018, during the public meeting on "FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy" and to share our perspective on the topic of facilitating innovation to promote healthful eating patterns.

We applaud the Agency for convening a forum for this very important dialogue and the opportunity for public participation. USP's mission aligns closely with that of FDA–ensuring that safe, quality food ingredients are available, along with adequate information for informed decision-making by manufacturers, suppliers, and consumers.

We are committed to supporting FDA and other stakeholders as the Agency seeks to promote nutrition innovation. In particular, we feel that our activities in the development of public, science-based standards for food substances can play a vital role in helping the Agency, the food industry, and consumers in understanding the identity of food substances. In the following pages, we highlight the utility of food ingredient standards as a potential resource in this space.

Our comments focus on FDA's interest in standards of identity. Specifically, we wish to highlight the role of public standards in helping to establish that food ingredients are what they are represented to be – thereby enabling consumers and manufacturers to identify healthful products. Standards of identity can help ensure the purity and quality of ingredients as diverse as olive oil, honey, spices, and seasoning.

For nearly 200 years, USP has been building foundations essential to provide quality products to consumers by ensuring that manufacturers and regulators have access to the reliable standards needed to satisfy consumers' expectations. Our activities include the development of documentary standards for identity and quality, as well as the creation of reference materials for analytical testing. USP develops standards through an open, transparent process with public participation and input from stakeholders including representatives from academia, industry, and government.

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USP publishes the *Food Chemicals Codex* (*FCC*)[1], which contains monographs for food substances that include tests, procedures, and acceptance criteria to ensure the quality, purity, and identity of such products. USP's well-established monograph system connects the standardized plain language name with key identity and quality attributes. Monograph standards and methods can support nutritional analyses needed to ensure that information (such as vitamin, mineral, calcium and iron levels) in the nutritional facts panel is accurate.

USP applauds FDA's dedication to innovation and sound scientific decision-making to advance public health in the foods space, and we are dedicated to advancing these efforts, through activities such as:

- The publication of more than 1,250 food substance monographs, covering a broad range of ingredients from probiotics and sweeteners to infant formula ingredients. Our scientists and expert volunteers are also working closely with stakeholders and FDA on standards for olive oil, honey, and dietary proteins.

- The development of 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. USP's current catalog includes more than 3,600 items, including more than 200 Reference Standards for food substances (e.g., amino acids, salts, sweeteners, and oils).

- Collaborating with FDA, industry, and others to develop and publish the *Food Fraud Mitigation Guidance*, available as an Appendix to the *FCC* and as a standalone free resource (http://www.usp.org/ffmg-form). The guidance offers a comprehensive framework to guide manufacturers and retailers in implementing effective mitigation approaches to safeguard the most fraud-vulnerable ingredients in their supply chain, with the ultimate goal of helping to ensure a product is not adulterated or contaminated.

- Collaborating with industry to develop and publish *Guidance on Developing and Validating Non-Targeted Methods for Adulteration Detection* as an appendix to the *FCC*. This guidance includes frameworks and tools that can be used to implement non-targeted analytic methods to assess food identity and quality.

Standards of identity and quality that are relevant, continually maintained, and up to date help support industry advancements and public safety. In carrying out our scientific work on a daily basis, we recognize and draw upon the strong collaboration and commitment of FDA, industry, and other stakeholders. Through our compendial

[1] *FCC* standards are referenced in over 200 FDA food ingredient and food additive regulations. *FCC* standards are also cited in USDA Commercial Item Descriptions, in which specified finished foods sold to the U.S. government must have ingredients that adhere to these standards—thereby helping to ensure the quality and identity of associated food ingredients and additives.

development efforts and ongoing work to develop tools to enhance food quality, USP seeks continued opportunities to collaborate with FDA and to serve as a resource in supporting nutrition innovation and enhancing public health.

USP stands ready to assist in any way that would be helpful. Again, thank you for the opportunity to comment. Should you have any inquiries related to these comments or to USP's capabilities in resources in the food quality area, please feel free to contact Elizabeth Miller, Pharm.D.,Vice President, U.S. Public Policy and Regulatory Affairs, at ehm@usp.org; (240) 221-2064.

Sincerely,

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