



U.S. Pharmacopeia
The Standard of Quality™

June 1, 2010

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

Re: Docket No. FDA-2010-N-0195-
Risk Profile: Pathogens and Filth in Spices: Request for Comments

Dear Sir/Madam:

The Food and Drug Administration (FDA) has requested comments and scientific data and information that would assist the agency in its plans to conduct a risk profile for pathogens and filth in spices.

While we acknowledge the productive steps that have been taken by industry and government (including pending legislative food provisions, such as third-party certification programs), the United States Pharmacopeial Convention (USP) believes the risk of economically motivated adulteration of ingredients, including spices, has been and continues to be a threat to consumers and law-abiding manufacturers.

While we understand that the purpose of the FDA's risk profile review is to ascertain the current state of knowledge about spices contaminated with microbiological pathogens and/or filth, and the effectiveness of current or potential new interventions, we hope the FDA will also consider in its inquiry adulterants that do not have a microbiological origin.¹

USP believes that 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. When adulteration occurs, it is at first unknown whether it could create a significant health risk to the consumer (such as the presence of Sudan Red Dyes in chili powder or lead salts in paprika powder), or it could defraud the consumer only economically (such as the presence of undeclared defatted paprika powder).

Compendial standards (and associated chemical reference materials) and voluntary verification programs can offer efficient sources of information for

¹ *As the recent adulteration of pet food and baby food by melamine and cyanuric acid evidenced, economically-motivated adulteration can pose risk to the health of the consumers, and industry is also affected: recalls can cost the industry hundreds of millions of dollars, not including the damage to brands and reputation. See American Spice Trade Association (ASTA) White Paper: "The economic adulteration of spices can have serious implications. In some instances, spices have been adulterated with highly-toxic materials such as lead-bearing pigments and other unapproved color additives. In those instances adulteration may have serious public health consequences." Available at <http://www.astaspice.org/files/public/SpiceAdulteration.pdf> (accessed 5-6-10).*

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the quality, purity and authenticity of food ingredients, including those that are commonly known as spices. By way of example, USP publishes quality standards for dietary supplements in its *Dietary Supplement Compendium (DSC)*, and for food ingredients, in the *Food Chemicals Codex (FCC)* (www.usp.org/fcc/). These compendial resources offer manufacturers a means to help assure the identity, authenticity and quality of their products.

*FCC*², now revised to a *Seventh Edition*, is a compendium of internationally recognized standards for the purity and identity of food ingredients. While *FCC* does not include monographs for spices, it does contain monographs for flavoring agents extracted from spices. USP acquired *FCC* in 2006 from the Institute of Medicine; *FCC*'s written food standards, and accompanying physical (chemical) standards, complement USP's legally-recognized and FDA-enforced quality standards for drugs. *FCC* features about 1,100 monographs, including food-grade chemicals, processing aids, foods (such as vegetable oils, fructose, whey, and amino acids), flavoring agents, vitamins, and functional food ingredients (such as lycopene, olestra, and short chain fructooligosaccharides).

While the use of *FCC* is mostly voluntary in the United States, over 200 FDA regulations incorporate *FCC* standards, and other countries have similarly done so. In Canada, food additives must comply with relevant specifications in regulations issued by Health Canada. If no such regulations exist, food additives must meet the specifications of the *FCC Fourth Edition* "as amended from time to time." See *Canadian Food and Drug Regulations* under Section B.01.045(b). For Australia and New Zealand, the Food Standards Australia and New Zealand recognizes the *Sixth Edition* of the *FCC* as a primary source of identity and purity specifications for substances added to food, in Standard 1.3.4 *Identity and Purity* of its *Food Standards Code*. In Brazil, *FCC* standards are recommended, along with other standards. 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.

While USP does not have a food ingredient verification program, our two voluntary verification programs for dietary supplements are a useful model of the types of voluntary industry approaches that can be helpful. One program covers finished dietary supplements, <http://www.usp.org/USPVerified/dietarySupplements/>, and the other addresses dietary supplement ingredients, <http://www.usp.org/USPVerified/ingredients/>.

² In her recent address at USP's Convention on April 23, 2010 (see <http://www.fda.gov/NewsEvents/Speeches/ucm209514.htm>), Commissioner Hamburg noted the importance of *FCC* in setting standards for the identity and purity of food ingredients. At the Convention we also received direction from USP's primary oversight body, the USP Convention, to strengthen the role of *FCC* as a global compendium for food ingredients, increase the number of documentary standards and reference materials based on identified needs, and explore the feasibility and advisability of expanding the scope of *FCC*. We are striving to update our food ingredient standards to address issues such as economically-motivated adulteration (e.g. melamine), through a working group and strengthen interactions with FDA on science-based approaches, including new technologies to enhance detection capabilities. With melamine there are, of course, a number of scientific and practical challenges that exist.

These programs help ensure consumers receive quality products. We also operate verification programs for excipients and pharmaceutical ingredients (see <http://www.usp.org/USPVerified/pharmaceuticalIngredients/>) (again, a useful example, since some excipients can serve as food additives).

We hope that FDA will continue to encourage the use of such tools to improve the safety net. Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Williams", written in a cursive style.

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