



U.S. Pharmacopeia
The Standard of Quality™

June 20, 2011

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

Subject: Comments of USP on "Periodic Review of Existing Regulations:
Retrospective Review Under E.O. 13563."
Docket No. FDA-2011-N-0259

Comments directed specifically at FDA regulations incorporating by reference out-of-date *Food Chemicals Codex* food standards for additives and substances Generally Recognized as Safe

Dear Sir/Madam:

The United States Pharmacopeial Convention (USP) appreciates your review of regulations pursuant to Executive Order 13563 to make sure they reflect public health needs and advances in innovation. Currently, FDA incorporates by reference out-of-date editions of the *Food Chemicals Codex (FCC)* in regulations for food additives and substances Generally Recognized as Safe (GRAS) (*Code of Federal Regulations (CFR) Parts 170, 172 and 184, respectively*). Specifically, over 200 *FCC* standards and test methods from the **2nd, 3rd, 4th and 5th Editions** are incorporated by reference in the *CFR*. These regulations need to be revised to incorporate by reference the most up-to-date standards contained in the recent *FCC 7th Edition*, and future editions concurrent with their release.

In 2006, USP purchased the *FCC* from the Institute of Medicine (IOM) of the National Academy of Sciences and subsequently published the *FCC 6th Edition* in 2008. In 2010, USP published *FCC 7th Edition* and intends to publish the *8th Edition* in 2012. Because *FCC* standards help assure the quality and safety of food ingredients and food additives, it is important that industry adhere to the most recent *FCC* standards rather than to out-of-date ones that are not used or unavailable. Notably, USP does not maintain the *FCC 3rd, 4th and 5th Editions* and cannot provide them on request. USP archived the *FCC 6th Edition* ninety (90) days after the publication of the *7th Edition* and makes it available only upon specific request. Only the *FCC 7th Edition* is currently available to the public and industry.

Out-of-date standards and methods can also cause confusion to industry and foster inconsistency and lack of uniformity. In addition, some of the equipment required in out-of-date *FCC* standards is not used by industry and is not readily obtainable. Most critically of all, consumer safety can be jeopardized because of the risk posed by out-of-date analytical methods, procedures, techniques and equipment in determining acceptable levels of use and consumption of food ingredients and additives. For example, prior to the *FCC 7th Edition*, heavy metals were only determined as the sum of a set of heavy metals (set to not exceed 10 mg/kg). Now, all heavy metals are to be determined by modern analytical tools and allowed levels have been reduced where warranted in specific cases (e.g., the limit of lead in *FCC 7th Edition* is 2 mg/kg). This underscores the need to incorporate by reference in the *CFR* the most up-to-date *FCC* standards possible.

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To strengthen FDA's capabilities for food ingredient and additive standards and ensure they are up-to-date, USP has filed a Food Additive Petition and a Citizen Petition to request that FDA update the food additives and GRAS regulations to conform to specifications in *FCC 7th Edition*. USP's Food Additive Petition was submitted to FDA on May 7, 2010, and covers 39 food additive regulations. The Office of Food Additive Safety (OFAS) within FDA's Center for Food Safety and Applied Nutrition (CFSAN) has evaluated the petition and we are currently responding to comments. The Citizen Petition was filed on March 15, 2010 to amend 168 Generally Recognized as Safe (GRAS) regulations that incorporate by reference specifications from out-of-date *FCC* editions. On September 16, 2010, USP received a letter from Mitchell Cheeseman, Ph.D., Acting Director of CFSAN, in accordance with the 180-day rule (21 *CFR* § 10.30(e)(2)), indicating that no decision had been reached on our citizen petition. We will continue to be in contact with FDA on this issue.

We were encouraged by Commissioner Hamburg's mention last year <http://www.fda.gov/NewsEvents/Speeches/ucm209514.htm> of the value of USP's food ingredient standards. We have had many positive interactions with FDA and stakeholders regarding *FCC* standards and we appreciate FDA's commitment to food quality. We look forward to continued discussions.

Thank you for the opportunity to submit this comment. Please let us know if we can be of further assistance. You can contact Director of Government Affairs Ben Firschein on my staff at baf@usp.org, (301) 816-8235.

Sincerely,



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