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U.S. Pharmacopeial Convention

June 11, 2015

Dr. Stephen Ostroff, Acting Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Acting Commissioner Ostroff:

The United States Pharmacopeial Convention (USP) appreciates your efforts in support of public health. Our organization has recently been involved in heightened discussions about the value of public standards as they relate to the integrity of dietary supplements. We have become increasingly aware of regulatory interest in these products—as manifested by recent efforts by state attorneys general to apply state consumer protection laws; Congressional discussions; and heightened accounts in the media.

Like the Food and Drug Administration (FDA), USP often finds itself called upon to be a helpful resource with respect to science and standards: this has been especially true during the current debate on supplements. While differing perspectives exist about how best to ensure these products meet standards of identity and quality—whether through regulatory or more voluntary means, USP believes a dialog is constructive and important.

Given the long history of collaboration between USP and FDA, our public health mission and our frequent role as a convener, we are interested in exploring with you ways to bring people together and build consensus on these important issues. In addition to the formal role in law between FDA and USP, as expressed through the Federal Food, Drug, and Cosmetic Act, USP has had a number of meetings and interactions with FDA over the years regarding standards for the authenticity, quality, and purity of food ingredients and dietary supplements. USP was encouraged by the recent remarks of Deputy Commissioner Howard Sklamberg at the USP Convention about the spirit of collaboration that exists between FDA and USP.

We would also like to find new ways to involve industry and other stakeholders in public discussions that often surround the adoption of new standards. For example, USP is working on standards and tests specifically designed to address the issue of adulterated drugs in dietary supplements; **Proposed General Chapter <2251> Adulteration of Dietary Supplements with Drugs and Drug Analogs** is published in the Pharmacopeial Forum and open for public comment. As with all standards committees, we appreciate the participation of an FDA liaison in developing the standard. This will be a tool that will be available to industry and regulators to help identify these dangerous ingredients and prevent them from reaching consumers.

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USP appreciates concerns about the increasingly global nature and complexity of modern supply chains. To help bridge this gap, USP created the USP Ingredient Verification Program. The number of participants is growing. In meetings with FDA staff we have conveyed that USP's food ingredient standards as well as its dietary supplement standards are used in the U.S. and throughout the world to help ensure the quality of foods and dietary supplements. USP's verification programs for both dietary supplement ingredients and finished products provide an additional level of quality assurance for both manufacturers and consumers.

We look forward to continuing the discussion with FDA and we would like to explore the possibility of a meeting to discuss these issues. If this is amenable to you, Christine Feaster, Vice President and Head of Strategic Marketing and Program Operations-Dietary Supplements & Herbals will be in touch with your office to schedule. Alternatively, Christine can be reached at (301) 230-6300 or cef@usp.org .

Sincerely,

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer