



U.S. Pharmacopeia
The Standard of Quality™

January 14, 2011

Dr. Patrick Gallagher, Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, MD 20899-1000

Re: Request for Information, National Institute of Standards and Technology,
Department of Commerce, Docket Number 0909100442-0563-02, submitted to
SOS_RFI@nist.gov

Dear Dr. Gallagher:

The United States Pharmacopeial Convention (USP) thanks you for the opportunity to comment on Federal agencies' participation in standards and conformity assessment activities and programs. Specifically, you ask what methods of engagement are used by Federal agencies to participate in private-sector-led standards development, how transparent is each method, how effective methods are, and how methods can be improved.

As a private not-for-profit volunteer-led standards-setting organization, USP appreciates the importance of initiatives to increase the uptake of private standards into the federal government. We recognize the significant mission of the National Technology Transfer and Advancement Act and the work of the Sub-Committee on Standards under the National Science and Technology Council's Committee of Technology.

USP wishes to comment on the many positive standards-setting interactions we have had with the Food and Drug Administration (FDA). Those interactions are highlighted below and in Attachment 1. Opportunities exist for enhanced cooperation, as we are discussing with the FDA. The adoption of national public standards is of great importance as we work to enhance the safety net and protect the public; we therefore appreciate the FDA and its unique public health mission.

We previously described to you our standards-setting programs (Attachment 2). While USP standards for drugs and pharmaceutical ingredients are recognized in law and therefore largely fall outside of the category of voluntary consensus standards, the open, transparent, and highly participatory process used to develop them is similar in many ways to that of voluntary consensus standard setting organizations. It involves close cooperation with the FDA and stakeholders, since our drug quality standards are enforceable by that agency.

Conversely, conformance to USP's dietary supplement and food ingredient standards is not generally required by law—and they are thus voluntary. They adhere to the same open processes and stakeholder input as with our drug quality standards. Nevertheless, FDA references USP dietary supplement standards in a number of areas related to nutrition and also cites USP food ingredient standards in over 200 regulations. We have encouraged FDA to update references to the most recent version of these standards in USP's *Food Chemicals Codex (FCC)*, recently published in a *Seventh Edition*.

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We are working to ensure that as soon as standards need to be added or updated, we can do so and they are taken up by FDA—a more or less automatic process for drugs, and an emerging one for food ingredients as we experiment with food additive petitions and other mechanisms.

USP is largely dependent on industry to provide it with the information and candidate materials needed to create up-to-date standards. We therefore appreciate FDA's continued interest in collaborating with USP to encourage industry to work closely with us to update standards—heparin and glycerin are recent success stories.

We noted the Commissioner's comments at the USP Convention in April 2010 highlighting the need for continued cooperation between FDA and USP in support of up-to-date public standards. She said: "Together, we have tackled a variety of important projects. We have collaborated on scientific standards for drugs, medical devices, and other products; created a Reference Standards program as well as standards for insulin and antibiotics; and established reporting programs for drugs and medical devices. But there is still a great deal of work to be done." The Commissioner also remarked, "In the coming years, we would like to share information about ways to help manufacturers make and market safe dietary supplements. We would also work together to develop methods to detect contaminants, including pharmaceuticals, in dietary supplements and foods."

Among the resolutions adopted by Convention delegates at that meeting was Resolution 3, which calls on USP to strengthen its relationship with the FDA (<http://www.usp.org/aboutUSP/resolutions.html>).

We believe FDA can play an even more pivotal role in encouraging industry to work with USP to develop the new methods needed to update monographs. In addition, we are exploring with FDA ways it can provide input earlier in the process and furnish more complete information that will allow modernization proposals to be finalized more quickly, and we have developed working groups and other activities. ***These efforts by USP and its volunteers do not cost taxpayer dollars and they save the government needed resources while improving the safety net. They are a model for additional public-private partnerships in an era of scarce resources.***

Thank you for the opportunity to comment.

Sincerely,



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

ATTACHMENT 1: SUMMARY OF FDA-USP INTERACTIONS

I. Compendial Interactions with the Food and Drug Administration

As the regulatory authority for drugs and many foods in the United States, the Food and Drug Administration (FDA) is a major stakeholder in USP's activities. Traditionally, USP and FDA have worked together to develop standards and to ensure their appropriate implementation, primarily through the FDA Compendial Affairs Office. Paul Seo, Ph.D., serves as FDA's Director of Compendial Operations. Dr. Seo coordinates FDA's representation on USP Expert Committees and Expert Panels as well as FDA's comments on USP's standards proposals. He also coordinates responses to day-to-day questions posed by USP's scientific liaisons regarding the FDA approval status. There currently are 66 FDA liaisons who are assigned to USP's 20 Expert Committees. USP anticipates that the number of FDA Liaisons will grow as Expert Panels are formed throughout the cycle.

In addition, FDA representatives participate in USP Workshops, Annual Meetings, Stakeholder Forums, Project Teams, and other special topic meetings.

At the beginning of the 2005-2010 cycle, FDA employees served both as members of and FDA Liaisons to USP's Expert Committees and Advisory Panels. In 2007, as a result of FDA's revision to its Staff Manual Guide (SMG), FDA employees serving as members of USP Expert Committees and Advisory Panels transitioned to FDA Liaisons and assumed an advisory, non-voting role on USP's Expert Committees. This transition arose from USP's long-standing policy that members of the Council of Experts participate in based on their expertise and not the organization they represent, which was no longer possible for FDA under the SMG (which required FDA employees to serve solely as FDA representatives).

A new CRADA between USP and FDA's Office of Regulatory Affairs (which is pending approval at FDA) has as one of its objectives the development of new methods for monograph modernization. We recognize that FDA's laboratory resources, like USP's, are limited, but believe that by coordinating our efforts, more can be accomplished in a shorter amount of time.

II. USP-FDA Quarterly Meetings

Since March 2006 USP and FDA leadership have met quarterly to discuss compendial and other topics of mutual interest and to promote collaboration between the organizations. The FDA delegation is led by Helen Winkle, Director, Office of Pharmaceutical Science, Center for Drug Evaluation and Research. Ms. Winkle represents the Standards Working Group, which is an agency-wide group that addresses how FDA works with standards-setting bodies.

Several working groups have emanated from the Quarterly meeting, including the Melamine Working Group, and two new groups, the Compounding Working Group and the Monograph Modernization Working Group. These working groups come together to assure that there is agency and USP alignment in the development and revision of key compendial standards. A model for this activity, although it was not considered to be a Working Group per se, was the initial work that USP did, at FDA's request, on the modernization of the heparin monographs.

III. Office of the Commissioner and Other Interactions

In addition, USP has had various meetings with the Commissioner and her deputies, as circumstances warrant and permit.

USP has had multiple meetings with the Center for Food Safety and Applied Nutrition (CFSAN) and FDA's Office of International Programs. USP and FDA have significantly improved awareness and mutual efforts across the globe as a result of new relationships and communications we established with FDA's Office of International Programs staff in headquarters as well as in China, India, Europe, and Latin America and the Caribbean.



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**ATTACHMENT 2: LETTER FROM ROGER L. WILLIAMS, M. D. TO
DR. PATRICK GALLAGHER, MAY 19, 2010**

May 19, 2010

Dr. Patrick Gallagher
Director
National Institute of Standards and Technology
100 Bureau Drive, Stop 1000
Gaithersburg, MD 20899-1000

Dear Dr. Gallagher:

Speaking on behalf of the United States Pharmacopeial Convention (USP), I thank you for attending the USP Convention in April. It was nice to meet you at our networking break. Bill Koch and Mat Heyman have been keeping me updated on recent discussions with Dr. Willie May and others at the National Institute of Standards and Technology (NIST) which hopefully will lead to mutually beneficial interactions on specific areas where our organizations have complementary roles. In fact, I understand that a team of NIST and USP staff are meeting this week.

I would also like to congratulate you on the recent creation of the Subcommittee on Standards under the National Science and Technology Council's Committee on Technology. We support this important initiative to further integrate privately-adopted standards into the federal government. We believe this will play a beneficial role in furthering public health, science, and commerce.

As you know based on your participation at our Convention meeting last month, USP is a volunteer driven, not-for-profit, science-based standards-setting organization founded in 1820 by eleven physicians. USP's mission is to improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP public standards are set by more than 700 expert volunteers from around the world, who give freely of their time and talent to produce the *United States Pharmacopeia–National Formulary (USP-NF)* – official compendia for drugs recognized in federal law. USP works with the Food and Drug Administration (FDA), which enforces these standards. We also provide the reference standards, carefully measured chemical and physical samples, which are key tools used to help ensure adherence to written standards and quality assurance requirements.

USP's primary oversight body is the USP Convention itself, which meets at five-year intervals. The Convention has over 500 member groups,

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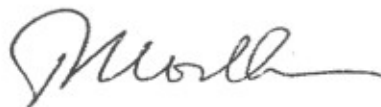
including governmental bodies, and individual members. This makes USP a unique group committed to assuring the quality and benefit of drugs and food.

While USP sets standards for drugs and pharmaceutical ingredients, technically, these standards largely fall outside of the category of voluntary consensus standards. Although the process used by USP to develop them is similar in many ways to that of voluntary consensus standard setting organizations, the standards are not considered voluntary because compliance is mandated under the Federal Food, Drug and Cosmetic Act. For this reason the Office of Management and Budget's Circular No. A-119 explicitly mentions *USP-NF* as an example of a non-voluntary standard—but this is not necessarily the case for all USP standards. We have also been exploring ways that parts of our standards-setting process might be adopted to a voluntary consensus-standards-setting model.

In addition to its standards for drugs, USP creates standards for dietary supplements and food ingredients. Dietary supplement standards are published as part of the *USP-NF*, which also contain USP's drug standards. USP's standards for food ingredients are published in the *Food Chemicals Codex*, which USP acquired from the National Research Council and Institute of Medicine and has now updated to a *Seventh Edition*. For the most part, conformance to USP's dietary supplement and *FCC* standards is not required by law, and thus they can be considered voluntary. These standards, if complied with, help assure the safety and quality of dietary supplements, dietary supplement ingredients and food ingredients.

If you would like more information please contact me or USP's Director of Government Affairs, Ben Firschein, baf@usp.org, (301) 816-8235.

Sincerely,



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