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May, 12, 2014

Office of Management and Budget
725 17th Street, NW
Washington, DC 20503
Submitted Electronically

Subject: Comments on "Proposed Revision of OMB Circular No. A-119, 'Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities'", Docket No. OMB-2014-0001

Dear Sir/Madam:

Thank you for the opportunity for the United States Pharmacopeial Convention (USP) to comment on the proposed revision to the above-captioned Circular on voluntary consensus standards. USP's mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. We have set standards for medicines since 1820, and also do so for dietary supplements and foods.

We strongly urge OMB to avoid over reliance on voluntary consensus standards and to provide the necessary flexibility and discretion for Federal agencies to continue to use standards developed by other means.

I. Statement of Concern

USP questions the revised Circular's strengthened preference for voluntary consensus standards over other types of voluntary standards (Page 5) and the directive that agencies use non-consensus standards only *in instances where there are no suitable voluntary consensus standards* (Page 20). Each type of standard has its place. The benefits of non-consensus standards, such as those set by USP in the area of health, include development through an objective, purely scientific process that utilizes the work of independent experts in close collaboration with stakeholders and government; and the rapid ability to adjust standards to confront public health emergencies[1], adapt to new industry practices[2], and keep up with evolving science and technology[3]. By contrast, voluntary consensus standards may not always take into account non-industry perspectives, and because they involve a longer development timeframe may also become quickly outdated. *Federal agencies should have the flexibility to utilize standards that work best, and not just "particularly in emerging technology areas" (Page 20).*

II. USP Standards

USP sets standards for drugs and pharmaceutical ingredients in the *United States Pharmacopeia-National Formulary* (*USP-NF*), and these standards fall outside of the category of voluntary consensus standards. Although the process used to develop

[1] E.g., adulteration of heparin and glycerin.

[2] E.g., testing procedures.

[3] E.g., standards for heavy metals (elemental impurities).

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them has similarities to voluntary consensus standard setting, such standards are not developed by consensus[4]; and they are not considered voluntary in the case of drugs because compliance with certain standards in *USP-NF* is mandated under the adulteration and misbranding provisions of the Federal Food, Drug, and Cosmetic Act (FDCA). USP additionally creates quality standards for dietary supplements and food ingredients, published in the *Dietary Supplements Compendium* (*DSC*) and the *Food Chemicals* Codex (*FCC*), respectively; they are also established through a non-consensus process. Dietary supplements have a certain role in law, when labeled "USP." *FCC* has no role in law, although the U.S. Food and Drug Administration (FDA) has incorporated by reference *FCC* standards for food ingredients in over 200 regulations.

III. Ensuring Incorporation of Up-to-Date Standards

USP is equally concerned that even when federal regulations incorporate standards by reference, such regulations can become outdated, adversely impacting public health, safety, and commerce (page 6, "Ensuring the Timely Updating of Standards"). With *FCC* we have experienced challenges in ensuring that USP standards for food additives and Generally Recognized As Safe ("GRAS") substances incorporated by reference in FDA regulations are updated and do not reference an antiquated out of print edition. While we have seen recent progress by FDA in updating some *FCC* references particularly with food additive standards, other *FCC* references in the GRAS regulations remain extremely outdated despite a pending Citizen's Petition filed by USP in 2009 to update them. Therefore, USP supports that each agency undertake a standards-specific review of incorporated standards every 3-5 years, or as otherwise appropriate such as when advised by stakeholders (Section 6(o), Page 32), to help ensure incorporated standards remain up-to-date.

IV. Conclusion

While USP appreciates OMB's acknowledgement that standards developed by voluntary non-consensus bodies can be helpful (page 4), we believe the revised language in the Circular will discourage the beneficial use of those standards. Federal agencies should have the flexibility to use standards that advance their mission.

Thank you for considering our views. Should you require more information, our staff contact is Ben Firschein, USP's Director of Government Affairs and Policy, baf@usp.org, (301) 816-8235.

Sincerely,

Ronald T. Piervincenzi, Ph.D.
CEO and Chair, Council of Experts

[4] USP standards are established by independent volunteer experts with strict rules governing conflict of interest and substantial opportunity for public notice and comment and stakeholder engagement. FDA staff serve as nonvoting government liaisons on USP Expert Committees and Advisory Panels; feedback from regulatory agencies is very important to this process.