

## VIA ELECTRONIC SUBMISSION

April 15, 2019

Food and Drug Administration  
Division of Dockets Management  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2018-D-4417 for “CDER’s Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.”**

Dear Sir/Madam,

The United States Pharmacopeia (USP)<sup>1</sup> appreciates the opportunity to comment on the Food and Drug Administration’s (FDA or the Agency) draft guidance, “CDER’s Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.” USP has also provided comments on the final guidance from the Center for Biologics Evaluation and Research (CBER), “Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research.”<sup>2</sup>

USP believes that voluntary standards informally recognized through the Agency’s proposed program can complement compendial standards; each type of standard has its place and appropriate role in promoting public health. For many years, the Federal government has supported consensus standards,<sup>3</sup> and USP looks forward to continuing to engage in these complementary standard setting activities working with FDA, industry, and practitioners to identify public health needs and relevant standards to address such needs.

USP compendial standards are recognized in the Federal Food, Drug, and Cosmetic Act (FD&C Act). They are developed through an open, transparent, expert-based process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology. The process utilizes the work of independent experts in close collaboration with stakeholders and government agencies, such as FDA. We appreciate our long-standing relationship with FDA.

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<sup>1</sup> USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines, foods, and dietary supplements. Through a longstanding collaboration with FDA, we have worked continuously to benefit public health through accessible quality medicines.

<sup>2</sup> Docket no. FDA-2017-D-6535.

<sup>3</sup> Although the process used to develop USP compendial standards has similarities to consensus standard setting, such standards are not developed by consensus. They are established by independent volunteer experts with strict rules governing conflict of interest. There is also substantial opportunity for public notice and comment and stakeholder engagement.

We appreciate the acknowledgement in the draft guidance that CDER's informal recognition program will not apply to statutory and regulatory standards that are legally binding, such as certain provisions of the FD&C Act relating to USP. We note that FDA expressly addresses in the draft guidance situations where both an enforceable USP standard and a CDER-listed voluntary standard exist for the same purpose. Although the draft guidance reiterates no impact on the regulatory status of the USP standard, the language states that CDER may informally recognize alternative standards that are "comparable to the USP standard or that provide advantages over the USP standard."<sup>4</sup> We would appreciate exploring opportunities to engage with the submitters of such standards, and with FDA, in a manner to minimize developing separate standards that serve the same purpose and to help ensure efficiency and clarity.

We welcome an opportunity to meet with the Agency to discuss ways to support product quality and innovation through the application of standards that exist within the framework of the FD&C Act and voluntary standards that help ensure reliability, predictability and promote the quality of medicines.

Thank you again for the opportunity to comment. For more information, please contact Elizabeth Miller, Vice President, U.S. Public Policy and Regulatory Affairs, at [ehm@usp.org](mailto:ehm@usp.org); (240) 221-2064.

Sincerely yours,



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<sup>4</sup> Draft Guidance, at page 7 (Section VI., H.).