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-2017-D-6535 for ''Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research; Guidance for Industry.''

Dear Sir/Madam,

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 USP has also provided comments on the draft guidance from the Center for Drug Evaluation and Research (CDER), "CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical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

As indicated in our comments on CDER's draft guidance, USP would like to emphasize its continued support for the use of voluntary standards. We believe that voluntary standards can complement USP informational standards[3] and applicable compendial quality standards.

We appreciate FDA's clarification in the CDER draft guidance that CDER's proposed program to informally recognize voluntary consensus standards will not apply to statutory and regulatory standards that are legally binding, such as certain provisions

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[1] USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines. Through a longstanding collaboration with FDA, we have worked continuously to benefit public health through accessible quality medicines. USP's expert-based process enables the development and revision of standards to address public health emergencies, adapt to new industry practices, and reflect evolving science and technology.

[2] Docket No. FDA-2018-D-4417.

[3] The CDER draft guidance states, "Although much of USP and NF is legally enforceable, the USP general chapters numbered <1000> to <1999> (general informational chapters) are informational and generally do not contain any mandatory requirements (see USP General Notices 3.10, Applicability of Standards)." These informational standards include those targeted to product families and classes and intended to address common quality challenges and establish baselines for analytical performance associated with technologies and methodologies used by multiple manufacturers.

of the Federal Food, Drug, and Cosmetic Act (FD&C Act) relating to USP.[4] We understand that CBER's policy on the use of voluntary consensus standards similarly does not apply to such statutory and regulatory standards that are legally binding.

We note that the CBER final guidance includes language that was not in the draft guidance.[5] Specifically, the final guidance states that "[c]ompendial standards may be used to support a regulatory submission once CBER reviews and determines it is appropriate."[6] USP compendial standards include those that are required by law and those that are voluntary, or informational.[7] We appreciate that FDA supports the use of informational compendial quality standards in application submissions for biological products, as those statutory and regulatory standards that are legally binding would not fall under this statement or guidance.

USP standards are developed in an open, transparent process; are established by independent, scientific experts; and go through a public comment process. The independent experts work in close collaboration with stakeholders and government agencies, such as FDA.[8] Consensus and compendial quality standards play an important role in supporting public health.

USP has been working with stakeholders to identify the greatest needs in developing quality standards that are not compendially required.[9] In recent years, USP has hosted roundtables with industry and regulators to discuss common quality challenges encountered throughout the product development cycle.[10]

We welcome the opportunity to meet with FDA to discuss supporting product quality and innovation through the application of quality standards. We look forward to discussing how quality standards can be best leveraged for greater scientific clarity to advance our common goal of protecting and promoting public health.

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[4] These provisions apply to biological products just as they do to all other drugs, whether such biological products are approved under the FD&C Act or licensed under the Public Health Service Act (PHS Act). Section 351(j) of the PHS Act states that biological products licensed under the PHS Act are subject to the FD&C Act, other than the requirement of having an approved application under section 505 of the FD&C Act.

[5] This change did not go through a public comment period.

[6] Guidance, at page 8 (Section VI.A.5.).

[7] See footnote 3.

[8] For additional information on USP's commitment to biologics standards development, including a description of our process, see http://www.usp.org/biologics/development-process.

[9] USP continues to engage FDA, industry, and other stakeholders about how best to evolve our approach for biologics standards. See "USP's Commitment to Stakeholder Engagement Related to Biologics Licensed under the Public Health Service Act (PHSA)," at http://www.usp.org/biologics/development-process.

[10] See executive summaries of roundtable discussions, at http://www.usp.org/biologics/events-training.

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; (240) 221-2064.

Sincerely yours,

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