VIA ELECTRONIC SUBMISSION

September 4, 2019

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

Re: Docket No. FDA–2019–D–1768; Harmonizing Compendial Standards With Drug Application Approval Using the United States Pharmacopeial Convention Pending Monograph Process; Draft Guidance for Industry; Availability

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Pharmacopeia (USP)[1] appreciates the opportunity to comment on the Food and Drug Administration's (FDA or the Agency) draft guidance, *Harmonizing Compendial Standards With Drug Application Approval Using the United States Pharmacopeial Convention Pending Monograph Process*.

We appreciate our longstanding relationship with FDA in support of public health and commend FDA on the issuance of this draft guidance to inform industry on USP's Pending Monograph Process (PMP). The PMP was developed in 2007 and redesigned in 2015 in close collaboration with FDA. This program provides a pathway for efficient integration of appropriate information into USP public quality monographs. It also helps facilitate effective communication and information sharing among FDA, USP, and industry. Ultimately, the program helps enable timely patient access to quality medicines. Since 2015, over 70 requests for monograph revisions have been processed under the PMP.

USP supports the Agency's efforts to foster access to generic drugs and to pursue initiatives that facilitate increased competition for prescription drugs. The PMP and the issuance of this draft guidance will advance this effort.

USP's public monographs help to facilitate competition because they provide drug manufacturers with public benchmarks for quality medicines. With this in mind, we are also collaborating with FDA, industry, and other stakeholders to further develop public quality standards for critical drugs with limited competition as part of the effort to broaden access to quality generic drugs. This can improve access to medicines and help consumers lower their health care costs.

The PMP can be utilized for: (1) revisions of existing *USP–NF* monographs; and (2) creation of new monographs. Application and drug master file (DMF) holders (in the

[1] 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.

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case of a drug substance) are encouraged to work with USP to revise any monographs associated with their application while under review by FDA. In cases in which there is no existing official *USP–NF* monograph for a specific drug product or drug substance, USP encourages applicants and DMF holders to submit a request to sponsor development of a new *USP–NF* monograph under the PMP while their associated application is under review by FDA.

USP continues to support the Agency's efforts to expedite drug development to improve patient access to medicines. We look forward to continuing to work with FDA on refining the PMP, making it as effective as possible, and to collaborate on providing resources and training on this topic. Additional information can be found on the Pending Monograph website, at https://www.uspnf.com/pending-monographs.

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,

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