

USP applauds FDA's guidance encouraging industry use of the USP Pending Monograph Process to accelerate access to generic medicines

FDA guidance published in the Federal Register on July 10, 2019, encourages manufacturers to use the USP program in parallel with the FDA drug approval process

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Rockville, MD – July 17, 2019 – A new guidance document from the U.S. Food and Drug Administration (FDA) published in the Federal Register on July 10, 2019, "[Harmonizing Compendial Standards with Drug Application Using the USP Pending Monograph Process Guidance for Industry](#)" encourages manufacturers with a drug application for approval by the FDA to petition for a USP monograph change while their application is going through the FDA approval process.

Created in close collaboration with the FDA, the [USP Pending Monograph Process](#) (PMP) is designed to optimize time efficiencies by enabling drug manufacturers to work with USP on monograph revisions or to develop a new monograph during the FDA drug application approval process. In 2015, USP launched a revised version of the PMP to encourage information sharing and further streamline the work of FDA, USP, and manufacturers with the ultimate goal of increasing access to generic medicines.

"This program is just one example of the long-standing partnership of USP and FDA," said Elizabeth Miller, vice president, US Public Policy and Regulatory Affairs. "We have worked in close collaboration with FDA since its founding to help ensure patients have access to quality medicines."

The PMP has been promoted to manufacturers in a variety of ways and, as of 2015, USP has received over 70 requests for monograph revisions. "We are pleased that FDA is releasing its guidance that complements our efforts to encourage participation in the USP Pending Monograph Process," said Anthony Lakavage, senior vice president Global External Affairs. "We are confident that FDA's voice will generate significant additional participation and is the 'shot in the arm' we've been waiting for to more fully optimize this program."

USP monographs, also known as public quality standards, reflect the quality expectations for medicines approved by the FDA and are revised to reflect new innovations. They are utilized to help ensure patient safety, accelerate generics development, and to identify and remove poor-quality medicines from the market, including those manufactured outside the US. Public quality standards support generic competition by providing public benchmarks for a quality medicine. Manufacturers rely on USP standards to increase regulatory predictability and reduce the time and cost of drug development.

The USP Pending Monograph Process is one of many examples of USP's collaboration with the FDA to increase access to generic medicines. In addition, USP has been working with FDA, the Association for Accessible Medicines (AAM) and patient groups to advance FDA's Drug



Competition Action Plan (DCAP) in developing public quality standards for off-patent medicines without a generic version. More information on USP's collaboration to support the Drug Competition Action Plan can be found at www.usp.org/generics.

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people worldwide. For more information about USP, visit www.usp.org