VIA ELECTRONIC SUBMISSION

December 20, 2024

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Reauthorization of the Over-The-Counter Monograph Drug User Fee Program; Public Meeting; Request for Comments (FDA Docket No. FDA-2023-N-3575)

Dear Sir/Madam:

The United States Pharmacopeia (USP) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) recent public meeting regarding the reauthorization of the Over-The-Counter Monograph Drug User Fee Program (OMUFA). USP is an independent, scientific, global non-profit organization founded in 1820 and dedicated to building trust in medicines through rigorous science and public quality standards. We are guided by approximately 500 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention. A core pillar of USP's mission is to help strengthen the global supply chain so that medicines are available when needed and meet quality standards as expected and required.

General Comments

As mentioned above, our comments concern the recent OMUFA II public meeting and, specifically, the proposed changes to the OTC Monograph Order Request (OMOR) process and corresponding changes to testing methods within FDA's OTC monographs.

We would like to emphasize the role of compendial standards to help ensure the quality and consistency of OTC drug products. USP compendial standards define the acceptable quality, purity, strength, and identity of pharmaceutical ingredients and finished products, including OTC drugs. These standards are recognized in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and are developed through an open, transparent process that allows for adaptation to new industry practices and evolving science and technology. This process involves independent experts working closely with all stakeholders, including the FDA, to address public health needs. Moreover, the process offers the ability to adjust quickly to confront public health emergencies and facilitate innovation.

We urge engagement between the FDA, USP, and other stakeholders when considering modifications to test methods in FDA's OTC monographs. This engagement will help to minimize the development of separate, potentially inconsistent or conflicting standards serving the same purpose.

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We appreciate the opportunity to provide these comments and look forward to continued engagement with the FDA and other stakeholders on this important topic. Our goal is to support product quality and innovation by applying standards that exist within the framework of the FD&C Act and voluntary standards that help ensure reliability, predictability, and

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promote medicine quality. Should you need additional information about USP's response, please contact Brett Howard, Senior Director, U.S. Regulatory Policy, at brett.howard@usp.org or (301) 692-3296.

Sincerely,

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