VIA ELECTRONIC SUBMISSION

August 20, 2020

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

Re: Docket No. FDA-2020-N-1459; Generic Drug User Fee Amendments; Public Meeting; Request for Comments

Dear Sir/Madam,

The United States Pharmacopeia (USP)[1] appreciates the opportunity to provide comments to the Food and Drug Administration (FDA or agency) on the Generic Drug User Fee Amendments (GDUFA) program and suggestions regarding the next GDUFA program cycle.

Through a longstanding collaboration with FDA, USP has worked continuously to support public health through facilitating the development of quality medicines. USP supports efforts to foster access to generic drugs and to pursue initiatives that facilitate increased competition for drug products.

Quality Standards for Generic Drugs

USP standards provide valuable information to pharmaceutical manufacturers to support the early development of new or generic drug products and address common quality issues. Standards and associated analytical methods complement the role of abbreviated regulatory pathways, providing tools to create efficiency in product development and consistency across manufacturers. Studies indicate that public standards help foster a more competitive marketplace for medicines because the standards provide transparency on the quality expectation for a medicine, which helps new manufacturers come to market.[2] Methods associated with publicly available standards are important tools to support the development of generic drug products and market entry by multiple manufacturers to enhance competition. We support the continued use of quality standards in the review of abbreviated new drug

[1] USP is an independent, scientific, nonprofit organization dedicated to improving public health for medicines, foods, and dietary supplements. USP public standards are developed through an open, transparent, expert-based process, offering the ability to confront public health emergencies, adapt to new industry practices, and support evolving science and technology.

[2] One study found that on average, drugs with a public quality standard developed by USP had approximately 50% more generic manufacturers compared with medicines without such a standard, with associated savings of $11 billion. *See* Murimi-Worstell IB, Ballreich JM, Seamans MJ, Alexander GC, *Association between US Pharmacopeia (USP) monograph standards, generic entry and prescription drug costs*. PLoS ONE; 14(11): e0225109, at https://doi.org/10.1371/journal.pone.0225109 (Nov. 12, 2019).

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applications (ANDAs). Use of public quality standards is especially important for drug products developed in response to a public health emergency or drug shortage, and USP strongly supports the prioritization of ANDAs submitted for these reasons.

The GDUFA program can also be used to support FDA's Drug Competition Action Plan (DCAP) to improve the efficiency of generic drug development, review, and approval; and increase access to safe, effective, and quality generic drugs. FDA could explore mechanisms to promote the development of generic drugs that are on FDA's published list of Off-Patent, Off-Exclusivity Drugs with an Approved Generic to expedite access to drug products in the marketplace where competition is limited. USP is further supporting DCAP by reaching out to patient groups and industry to help identify gaps in access to critical therapies.[3]

Data on Quality and Information Sharing

USP supports the development and use of FDA's pharmaceutical quality assessment system, Knowledge-aided Assessment & Structured Application (KASA), to facilitate the review and assessment of drug applications by FDA. This knowledge management system promises to enhance the effectiveness, efficiency, and consistency of regulatory quality oversight through lifecycle management of products and facilities, and information sharing in a standardized and structured format. A critical component of the KASA initiative is the role of quality standards for the control of risk to quality.

Along with other recent FDA initiatives, KASA promises clearer regulatory expectations, enhanced transparency, and increased first cycle approval for generics with the goal of increasing access to more affordable medicines. USP supports further discussions on how KASA can support the GDUFA program and development of generic drugs, e.g., by holding public meetings and soliciting public comments.

Advanced Manufacturing

USP supports the development and adoption of advanced manufacturing technologies and analytical tools to increase patient access to quality drugs, as part of the agency's overall effort to ensure a robust and reliable supply of quality medicines. FDA defines advanced manufacturing as a collective term for new medical product manufacturing technologies that can improve drug quality, address shortages of medicines, and speed time-to-market.[4] Continuous manufacturing is an approach that can lower manufacturing costs and physical footprint, compared to traditional batch manufacturing. Continuous manufacturing has the potential for fostering greater quality control and lower variability of manufactured product,

[3] USP launched a Call for Collaboration to advance shared priorities and support greater patient access to important drug therapies through our monograph development and modernization efforts. *See* https://www.usp.org/our-impact/generics/call-for-collaboration.

[4] Advanced Manufacturing, at https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing#whatisadvancedmanufacturing.

increased cost-efficiency of production, and enhanced flexibility in the production quantity and utilization of manufacturing lines.

While continuous manufacturing has been utilized by some innovator drug manufacturers, adoption overall by the broader pharmaceutical industry, and especially by generic manufacturers, has been slower. This is due in part to uncertain market factors, such as return on investment, regulatory uncertainty, and additional needs for a workforce trained in these new technologies.

USP recommends that the agency work with stakeholders, e.g., through public meetings and soliciting public comments, to further understand potential barriers and regulatory hurdles that may hinder greater adoption of these technologies by generic manufacturers, as well as steps that could provide incentives for adoption of these technologies.

USP is currently engaging with a broad group of stakeholders, including academic research centers and manufacturers, to identify and articulate appropriate standards and practices that will make advanced manufacturing more accessible and achievable for industry uptake. We intend to further discuss with this group recommendations for GDUFA science and research priorities and projects for the next fiscal year and would appreciate the opportunity to share those with the agency.

USP looks forward to continuing to engage with FDA and all stakeholders on facilitating the adoption of new technologies to support increased production and availability of quality generic medicines.

We thank the agency for the opportunity to provide comments on the GDUFA program, in particular, to emphasize our support for the use of KASA and continuous manufacturing to further quality in generic products. For more information, please contact Marissa Chaet Brykman, Esq., Director, U.S. Regulatory Policy, at marissa.brykman@usp.org; (301) 692-3660.

Sincerely yours,

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