ORAL COMMENTS AT PUBLIC MEETING

March 9, 2020

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

Re: Docket No. FDA-2019-N-6050 for "FDA/FTC Workshop on a Competitive Marketplace for Biosimilars"

My name is Fouad Atouf, and I am the Vice President of Global Biologics at USP, the United States Pharmacopeia. Thank you for this opportunity to present our comments on the competitive marketplace for biosimilars. 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 by facilitating broader access to quality medicines.

USP supports FDA's and FTC's efforts to foster access to biosimilars and to pursue initiatives that facilitate increased competition for biological products. Furthermore, we believe that our public quality standards serve an important role in fostering a competitive marketplace.

First and foremost, USP public standards help ensure quality drugs. In particular, USP public standards for insulin have been used by manufacturers for decades to meet quality expectations. USP standards provide valuable information to biologic manufacturers to support the early development of new or biosimilar products and address common quality issues. These standards can add flexibility by offering choices of analytical approaches. Furthermore, studies indicate that public standards help foster a more competitive marketplace for medicines after a medicine's patent life expires because the standards provide transparency on the quality expectation for a medicine, which helps new manufacturers come to market.

USP standards are developed in an open, transparent process; are established by independent, scientific experts; and take into account public input. These experts work in close collaboration with stakeholders and government agencies, such as FDA.

USP is committed to ensuring that our approach evolves with the science of biologics and the needs of stakeholders by developing solutions that support the adoption of emerging analytical tools for biological product innovation and competition. We are developing standards that are broadly applicable across biological products and delivering solutions to address the quality of raw materials and support analytical testing throughout the product lifecycle.

USP will continue to convene stakeholders to identify areas of need and improvement for the development of biological products. In recent years, USP has hosted roundtables with industry and regulators to discuss common quality challenges encountered throughout the biological product development cycle. In the next three to six months, we will be holding a series of roundtables that cover a variety of topics, including but not limited to, ensuring the global supply of biologics, insulins, and the role of genomics analyses in personalized medicines. We are interested in hearing from the FDA and FTC, any additional topics you would like to discuss with stakeholders.

Thank you again for the opportunity to present our perspective. We stand ready to work with the FDA, FTC, and stakeholders in facilitating competition and access to biosimilar products.

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