

VIA ELECTRONIC SUBMISSION

May 3, 2019

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

Re: Docket No. FDA-2013-D-1543 for “Nonproprietary Naming of Biological Products: Update.”

Dear Sir/Madam,

The United States Pharmacopeia (USP)¹ appreciates the opportunity to comment on the Food and Drug Administration’s (FDA) draft guidance, “Nonproprietary Naming of Biological Products: Update.”

USP supports FDA’s revised application of the naming convention for biological products licensed without a suffix and transition biological products, that such product names will not need to include a proper name that is a combination of the core name and an FDA-designated suffix. As mentioned in previous comments to FDA, USP remains concerned that the naming convention will apply to new biological products, including interchangeable products, as this may have unintended consequences.²

USP compendial standards³ are developed through an open, transparent, expert-based process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology. The process utilizes the work of independent experts in close collaboration with stakeholders and government agencies, such as FDA.

¹ USP is an independent, scientific, nonprofit organization dedicated to improving health through the development of public standards for medicines. USP’s longstanding collaboration with FDA has worked continuously to benefit public health through accessible quality medicines.

² See USP comments on the “Nonproprietary Naming of Biological Products” draft guidance (Docket No. FDA-2013-D-1543) submitted Oct. 26, 2015; USP comments on FDA’s proposed rule “Designation of Official Names and Proper Names for Certain Biological Products” (Docket No. FDA-2015-N-0648) submitted Nov. 12, 2015; and USP comments on the “Nonproprietary Naming of Biological Products” final guidance (Docket No. FDA-2013-D-1543) submitted Feb. 13, 2017.

³ USP compendial standards include those that are required by law and those that are voluntary, or informational. Informational standards include those targeted to product families and classes and intended to address common quality challenges and establish baselines for analytical performance associated with technologies and methodologies used by multiple manufacturers.

USP is committed to ensuring that our approach related to biological product standards evolves with the science of biological products. In addition, USP intends to address the needs of stakeholders, including patients, practitioners, industry, and regulators. We are developing standards that are broadly applicable across biological products and delivering solutions to address the quality of raw materials as well as the development of standards which support analytical testing throughout the product lifecycle.⁴

We welcome the opportunity to meet with FDA to discuss how USP's compendial process related to biological products can continue to help ensure product quality to advance our common goal of protecting and promoting public health.

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 yours,



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⁴ For additional information on USP's engagement with FDA, industry, and other stakeholders related to biological product standards development, including a description of our process, see "USP's Commitment to Stakeholder Engagement Related to Biologics Licensed under the Public Health Service Act (PHSA)," at <http://www.usp.org/biologics/development-process>.