April 27, 2018

Peter Marks, M.D., Director, Center for Biologics Evaluation and Research
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Marks and Dr. Woodcock:

USP appreciates FDA's comments on USP's proposed revision to the USP General Notices and Requirements[1] relating to nomenclature of biological products. In USP's comments[2] to FDA's Nonproprietary Naming of Biological Products, Final Guidance for Industry, USP made the commitment that once FDA finalized its naming convention, USP would work to ensure that official titles assigned by USP were aligned with FDA's approach, as envisioned by the Federal Food, Drug, and Cosmetic Act (FDCA) and reflective of our longstanding partnership with FDA. USP fully embraces the opportunity to dialogue with FDA and other stakeholders to explore potential resolutions that will achieve this objective and advance our common goals of promoting access to and protecting the quality of biological products.

In addition, USP remains committed to ongoing collaboration with the Agency to support successful implementation of the Biologics Price Competition and Innovation Act (BPCIA). As you know, BPCIA seeks to increase patient access to critical drugs through the creation of an abbreviated regulatory pathway for licensing biosimilar biological products. Numerous diverse stakeholders are working together to ensure that this goal is achieved. These efforts have generated robust dialogue on legal, regulatory, and scientific issues, engendering various perspectives that continue to evolve. USP appreciates FDA's readiness to engage on these issues as we believe working together is essential for determining appropriate paths forward — paths that recognize, reconcile, and unify the approaches required to ensure the success of BPCIA.

Public standards play a critical role in ensuring the quality of all drugs, including biologics, and facilitating access to them. Recognizing that there are unique aspects to biologics, USP has convened discussions with FDA, industry, and other stakeholders and evolved our approach to ensure that USP standards ultimately assist manufacturers and regulators in advancing the objectives of BPCIA. These interactions have highlighted the need for standards that are broadly applicable across product families and classes. USP's focus on this type of standard will help industry resolve quality-related challenges commonly shared among products within a

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[1] USP, Notice of Intent to Revise, General Notices and Requirements (September 29, 2017; updated October 05, 2017) (available at http://www.uspnf.com/notices/general-notices-requirements).
[2] USP comments to FDA: (1) February 13, 2017, regarding "Nonproprietary Naming of Biological Products, Final Guidance for Industry," Docket No. FDA-2013-D-1543; (2) October 26, 2015, regarding "Nonproprietary Naming of Biological Products, Draft Guidance for Industry," Docket No. FDA-2013-D-1541; (3) November 12, 2015, regarding Proposed Rule "Designation of Official Names and Proper Names for Certain Biological Products," Docket No. FDA-2015-N-0648.

biological class or family. As we have previously stated, USP is committed to deploying our resources to address this need and will not publish as official any new product-specific monographs for biologicals unless they have FDA and stakeholder support. At the same time, USP is implementing a process to facilitate early and sustained engagement with FDA and stakeholders on biologics to help ensure that standards will be relevant and useful.

The General Notices proposal is intended to avoid concerns about a product being deemed misbranded when a suffix is added to its name, with a particular focus on facilitating a flexible approach to USP's naming process for biologics. The proposal is aimed in particular at those products that are transitioning from the FDCA to the Public Health Service Act under the BPCIA, and as a result, are expected to be assigned suffixes by FDA.[3] Many of these products - including widely used medicines such as insulins - have USP monographs, which for decades have ensured consistency and quality for patients as these medicines evolved. As these products transition, this General Notices approach would ensure that these products do not lose the long-standing protection that has been afforded by their USP standards by aligning FDA-assigned names and suffixes with USP's official monograph titles.

USP acknowledges FDA's concerns expressed in its comments regarding the proposed approach and also notes the diversity of views expressed by other stakeholders in their comments on the General Notices proposal.[4] USP appreciates FDA's willingness, as stated in its comments, to have further interaction with USP on these issues. Therefore, in the spirit of working collaboratively with FDA and other stakeholders, USP will not move the General Notices proposal forward until USP has further engagement to better understand the implications of the General Notices proposal.

Please do not hesitate to contact Elizabeth Miller, Vice President U.S. Public Policy & Regulatory Affairs at ehm@usp.org or (240) 221-2064 for any additional information or questions, and we look forward to further discussion.

Sincerely,

Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer

[3] A transitional biological product is a biological product approved under section 505 of the Federal Food, Drug, and Cosmetic Act that will be "deemed to be a license" under section 351 of the Public Health Service Act (PHS Act) on March 23, 2020. Guidance for Industry: "Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009," March 2016 (available at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm490264.pdf).

[4] USP has made all comments submitted on its General Notices proposal available on its website at https://www.usp.org/usp-stakeholder-comments-biologics-nomenclature.pdf.