General Notices and Requirements Nomenclature of Biologics Proposal will be Deferred

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The General Notices and Requirements section of the United States Pharmacopeia and the National Formulary was published for public notice and comment in *Pharmacopeial Forum* 44(1) [Jan.–Feb. 2018] with a proposed revision to Section 2.20 Official Articles.

Based on comments received from stakeholders, the USP Council of Experts (CoE), which is responsible for revision of the General Notices, has decided to defer the portion of the proposal that addresses nomenclature of biologics. 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. In the spirit of working collaboratively with FDA and other stakeholders, USP will not move forward the portion of the General Notices proposal that addresses biological product nomenclature until USP has further engagement to better understand the implications of the General Notices proposal.

The CoE has decided to proceed to ballot only with the portion that addresses nomenclature of products with sensors. The text to be balloted will read:

> 2.20. Official Articles
> An official article is an article that is recognized in *USP* or *NF*. An article is deemed to be recognized and included in a compendium when a monograph for the article is published in the compendium and an official date is generally or specifically assigned to the monograph.
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> The title specified in a monograph is the *official title* for such article. Other names considered to be synonyms of the *official titles* may not be used as substitutes for *official titles*. For drug products that incorporate a sensor to detect that the product has been administered, the official title shall be the title specified in the relevant drug product monograph plus the words "with sensor".

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 Biologics Price Competition and Innovation Act (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 biological class or family. 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.

Should you have any questions, please contact Jessica Simpson (jcs@usp.org).