BRIEFING

General Notices and Requirements. This proposal is based on the version of the *General Notices* that will be official on August 1, 2020. Based on continued scientific dialogue and the issuance of additional FDA guidance documents, USP has decided to republish this *General Notices* revision for further stakeholder input.

- Revise *Section 2.20 Official Articles* to add the following language at the end of the second paragraph: "For a biologic product licensed under the Public Health Service Act, the *official title* shall be the title specified in the relevant monograph plus any prefix and/or suffix designated by the FDA unless otherwise specified in the applicable monograph."

Background: This proposed revision was initially posted in a Notice of Intent to Revise (NITR) in September 2017 (updated in October 2017) and as a proposed revision to the *General Notices* in *PF* 44(1) after the FDA's issuance of its final guidance, *Nonproprietary Naming of Biological Products* in January 2017. The final guidance described that biological products licensed under the Public Health Service Act (PHS Act) bear a nonproprietary name that includes an FDA-designated prefix and/or suffix. The prefix and/or suffix format was applicable to originator biological products, related biological products, and biosimilar products previously licensed and newly licensed under section 351(a) or 351(k) of the PHS Act. USP received numerous comments in response to the 2017 NITR. See https://www.usp.org/sites/default/files/usp/document/our-work/biologics/usp-stakeholder-comments-biologics-nomenclature.pdf. Recognizing that the agency's approach to naming was still evolving, USP deferred finalizing the proposal.

Proposed Revision: Based on varied stakeholder input, continued scientific dialogue, and the issuance of additional FDA guidance documents, USP has decided to republish this *General Notices* revision for further stakeholder input.

Continued Scientific Dialogue: USP continued to engage with our stakeholders in scientific dialogue on standards that would be most helpful and that advance our common goals of promoting access to and protecting the quality of biological products. Based on scientific engagements, USP will continue to focus on developing performance standards, which are applicable to classes of biologics (e.g., monoclonal antibodies or cell therapies), as well as standards for raw materials. USP has stated publicly that it will not publish as official any new product-specific monographs for biologicals unless they have FDA and stakeholder support. These commitments continue to stand.

Updated Regulatory Guidance: In March 2019, the FDA released a draft guidance, *Nonproprietary Naming of Biological Products: Update*. The draft guidance indicated that the FDA no longer intends to apply an FDA-designated suffix to: (1) current and pending biological products licensed under section 351 of the PHS Act without FDA-designated suffixes; and (2) transition biological products—products which will transition on March 23, 2020 from an approved application under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to a biologics license application under section 351 of the PHS Act. The draft guidance also indicated that the FDA intends to continue to apply an FDA-designated suffix to all biological products at the time they are licensed under 351(a) or 351(k).

Intent of the Proposed Revision: This revision will clarify the continued application of USP public quality standards to biological products, including originator, biosimilar, interchangeable, and transition biological products. Transition biological products will continue to be subject to the applicable public quality standards in the *USP–NF* with the same core name. This clarification is consistent with Congressional action over decades that first established and reaffirmed the requirement that medicines marketed in the United States adhere to the quality attributes expressed in USP's public quality standards.

This revision will help ensure that a biological product that is given an FDA-designated prefix and/or suffix has an applicable USP quality standard. This revision will be "self-executing," that is, a manufacturer will not need to take any steps to implement. At the same time, the additional language provides flexibility, making it possible to apply different compendial approaches in situations where products share the same core name but have different prefixes and/or suffixes.

Adherence to quality standards that are public and transparent gives healthcare practitioners, patients and others confidence in biologic medicines. Essential to the framework that safeguards the quality and safety of medicines in

the United States is the principle that public quality standards, required under the law, establish and articulate quality expectations for medicines. Since the enactment of the Federal Food, Drug, and Cosmetic Act nearly 100 years ago, we have been deeply committed to this responsibility.

As part of our ongoing engagement with and commitment to stakeholders, USP welcomes and encourages comments and feedback about the impact of this revision, particularly with respect to impact on transition biological products. USP will hold a stakeholder roundtable to solicit comments on this proposal.

Note that revisions proposed in the previous *PF* publication, *PF* 46(1) [Jan.–Feb. 2020], pertaining to *Sections 1. Title and Revision*, *2.10 Official Text*, and *3.10 Applicability of Standards*, are also visible below. These revisions are tagged below with the targeted official date of May 1, 2021. Comments on that proposal are being accepting through March 31, 2020. Comments on this 46(2) [Mar.–Apr. 2020] proposed revision to *Section 2.20* are being accepted through May 31, 2020.

Additionally, minor editorial changes have been made to update the text to current *USP* style.

(COE: J. Simpson.)

Correspondence Number—C249695; C237215

DocID: GUID-6E790F63-0496-4C20-AF21-E7C283E3343E_6