USP statement on monographs for biologics

April 2, 2018

Rockville, MD – USP is currently reviewing stakeholder comments to our proposed change to USP-NF Section 2.20 Official Articles of the General Notices and Requirements 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 suffix designated by FDA unless otherwise specified in the applicable monograph."

USP has stated that it will not develop a new monograph for a biologic unless there is stakeholder consensus supporting its creation, including the support of FDA. USP's proposed revision is intended to align compendial names with FDA's biologics naming approach and avoid potential issues for manufacturers and other stakeholders.

The proposed change has been open for comment in the USP Pharmacopeial Forum which enables the organization to incorporate feedback from the Food and Drug Administration (FDA), as well as a wide variety of stakeholders, including industry, researchers, health providers and others. The comment period ended March 30, 2018.

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