## General Notices and Requirements

**Type of Posting:** Notice of Intent to Revise
**Posting Date:** 29-Sep–2017; updated 05-Oct-2017*
**Expert Committee:** Council of Experts

In accordance with section 7.04(c) of the Rules and Procedures of the 2015-2020 Council of Experts, this is to provide notice that the Council of Experts intends to revise 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."

On January 13, 2017, FDA issued a Final Guidance, *Nonproprietary Naming of Biological Products Guidance for Industry* (Final Guidance). The Final Guidance describes "FDA's current thinking that biological products licensed under the Public Health Service Act bear a nonproprietary name that includes an FDA-designated suffix." The suffix format described in the Final Guidance is 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 Public Health Service Act (PHS Act). Consistent with the Final Guidance, FDA has now begun licensing biosimilars with unique FDA-designated suffixes.

In its comments to the FDA's proposed Draft and Final Guidance, USP acknowledged that once FDA decided on its naming convention, USP would work to ensure that official names assigned by USP were aligned with FDA. As FDA implements its naming convention set forth in the Final Guidance, the revision to Section 2.20 of the General Notices is intended to ensure consistency between USP and FDA in the naming of biological products licensed under the PHS Act (biological products). This revision will help address any potential compliance issues by ensuring that a biologic product that is given an FDA-designated suffix is not out of compliance with an applicable USP monograph. 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 suffixes. USP remains committed to advancing our common goal of protecting and promoting public health, and as such believes that it is important that FDA's naming convention is implemented in a consistent, coordinated way that resolves any discrepancy between names and avoids potential issues for manufacturers.

As USP continues to engage stakeholders, USP would welcome input related to this intended revision, including any compliance concerns, by

October 27, 2017. Please submit any input, questions or comments to Jessica Simpson, Manager, Compendial Operations (301-816-8231to JCS@usp.org).

***This notice was updated on October 5, 2017 to correct the placement of the proposed text within Section 2.20**