Description and Summary of Proposed Revisions to *General Notices and Requirements* Published for Comment in *Pharmacopeial Forum* 41(1) [Jan.–Feb.] 2015

Outlined below are brief descriptions and summaries of changes that are proposed revisions to the *General Notice*s; the text of the proposed changes is being published for public notice and comment in *Pharmacopeial Forum (PF)* 41(1) [Jan.–Feb. 2015]. Following opportunity for public comment on the *PF* proposal, and consideration and adoption by the Council of Experts Executive Committee, these General Notices revisions are anticipated to be included in *USP 39–NF 34* (publishing November 1, 2015, official May 1, 2016).

GENERAL NOTICES AND REQUIREMENTS

To better categorize content in the *General Notices,* USP proposes moving information about the hierarchy of official texts from this Section to Section 3.10 *Applicability of Standards*, paragraph three.

1. TITLE AND REVISION

USP has three Accelerated Revision vehicles, which are used on a periodic basis. Proposed text has been added to this section to better define each type of Accelerated Revision and to note the location of any Accelerated Revisions on the "Official Text" section of the USP Website (http://www.usp.org/usp-nf/official-text).

2. OFFICIAL STATUS AND LEGAL RECOGNITION

2.10 *Official Text*

With the increasing focus on electronic versions of the *USP–NF*, it is proposed that language be added to Section 2.10, acknowledging the status of both print and electronic versions, and specifying that in the event of any disparity, the *USP–NF* Online will be deemed to apply. Language also has been added to this section to specify that General Chapter citations in the *NF* refer to the General Chapters in the *USP*.

3. CONFORMANCE TO STANDARDS

3.10 *Applicability of Standards*

The *General Notices* apply to all official text in the *USP–NF*, but there are instances when requirements in a monograph differ from the *General Notices* or an applicable general chapter. The proposed text in the first paragraph clarifies the primacy of the monograph in these instances.

USP–NF users implement revised standards following publication but before their official date. Proposed language better defines this early adoption period and notes that this practice is allowed by USP, either the existing or revised standard may be complied with, unless stated otherwise.

To clarify that tests using multiple dosage units should not be considered statistical sampling, proposed language clarifies that it is not in these cases.

3.20. *Indicating Conformance*
Proposed language specifies that compounded preparations are also required to be appropriately labeled, noting any differences from compendial standards and using a non-compendial name if the product does not meet the compendial identity.

4. MONOGRAPHS AND GENERAL CHAPTERS
4.10. *Monographs*
The term “interchangeability” refers to a regulatory concept. Proposed language replaces “interchangeability” with “substitutability” to make clear that no regulatory claims are made.

4.10.10. *Applicability of Test Procedures*
The proposed text merges section 4.10.11 *Dissolution, Disintegration, and Drug Release Tests* with Section 4.10.10 *Applicability of Test Procedures* and differentiates between monographs with multiple tests, procedures and/or acceptance criterion and flexible monographs, which allow for the selection of tests.

5. MONOGRAPH COMPONENTS
5.20. *Added Substances* and 5.20.10. *Added Substances, Excipients, and Ingredients in Official Substances*
Proposed language in the text and Section titles clarifies that the requirement for use of a minimum quantity of added substances does not apply to ingredients in official preparations but it does, however, apply to official substances.

5.50.10. *Units of Potency (Biological)*
The proposed text clarifies the relationship between USP units and other existing international potency units, or those assigned by a regulator. The proposed language also reflects the fact that for some materials, like vitamins, the labeled units have been replaced by mass/balance assignments. The labeling of these units is also clarified in the proposed language.

8. TERMS AND DEFINITIONS
8.230.20. *Water in the Manufacture of Official Substances*
Water used in manufacturing is to meet drinking water requirements in the proposed language.

8.230.30. *Water in a Compendial Procedure*
The citation for water specifications has been updated to replace an outdated reference and now directs users to either *Reagents, Indicators, or Solutions* or General Chapter <1231> *Water for Pharmaceutical Purposes*.

8.240. *Weights and Measures*
Clarifying language has been proposed to ensure that the degree symbol (°) is always interpreted as Celsius unless otherwise noted.

It is common for centrifuge literature to refer to the unit of acceleration due to gravity as “g.” USP monographs also use “g.” The proposed change in the Weights and Measures chart from “g_n” to “g” aligns the *General Notices* with USP monographs and use of the unit in industry.

9. PRESCRIBING AND DISPENSING

9.10 *Use of Metric Units*

Proposed language does not allow for abbreviations to be used on labels or for prescription purposes. A clarification in the use of abbreviations is intended to reduce medial errors.

10. PRESERVATION, PACKAGING, STORAGE, AND LABELING

10 through 10.40.100.1

The subject matter that is currently addressed in Sections 10.40 through 10.40.100.1 has been included in General Chapter <7> *Labeling* and is being proposed for removal from *General Notices*. General Chapter <7> *Labeling* is anticipated to become official at the same time as these *General Notices*.