General Chapters: <659> Packaging and Storage Requirements, <661> Plastic Packaging Systems and Their Materials of Construction, <661.1> Plastic Materials of Construction, <661.2> Plastic Packaging Systems for Pharmaceutical Use

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Expert Committee: General Chapters—Packaging and Distribution

In accordance with section 7.05(c) of the Rules and Procedures of the Council of Experts, this is to provide notice that the Packaging and Distribution Expert Committee intends to revise the following General Chapters:

- <659> Packaging and Storage Requirements
- <661> Plastic Packaging Systems and Their Materials of Construction
- <661.1> Plastic Materials of Construction
- <661.2> Plastic Packaging Systems for Pharmaceutical Use

The purpose of the revisions will be to provide a three-year period for implementation of the requirements specified in General Chapters <661.1> and <661.2>, which otherwise will become applicable on May 1, 2017 through General Chapter <659>; to reinstate requirements previously expressed in General Chapter <661> during this three-year period; to enable early adoption of the requirements in General Chapters <661.1> and <661.2> at any time during the three-year period in lieu of meeting the reinstated <661> requirements; and to remove the exemption to General Chapters <661.1> for previously approved packaging systems.

The specific intended revisions are as follows:

- Delay until May 1, 2020 the implementation of new requirements of General Chapters <661.1> and <661.2> as currently specified in General Chapter <659>.
- Incorporate into General Chapter <661> the requirements previously specified in the *USP 38-NF 33* version of General Chapter <661>. Reference General Chapter <661> in General Chapter <659> to make these previous requirements applicable until May 1, 2020.
- Clarify in General Chapter <659> that early adoption of the requirements of <661.1> and <661.2> is permitted by USP, and that packaging systems in compliance with these requirements in advance of May 1, 2020 will no longer need to comply with the reinstated <661> requirements to be considered by USP to be in conformance with the *USP–NF*.
- Remove the current exemption to General Chapter <661.1> for plastic materials and packaging systems previously approved by a regulatory authority

The proposed revisions to the above-mentioned general chapters will be published as Revision Bulletins on Friday, April 28, 2017 and will become official on May 1, 2017, superseding all previously published revisions.

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