

[Notice of Intent to Revise: Revisions to Plastics Packaging Chapters <659>, <661>, <661.1>, <661.2>, and <1661>](#)

Type of Posting: Notice of Intent to Revise

Posting Date: 26–October–2018; revised 28–Dec–2018*

Targeted Official Date: August 1, 2020, USP-NF

Expert Committee: Packaging and Storage Expert Committee

In accordance with section 7.04(c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the General Chapters–Packaging and Distribution Expert Committee intends to revise:

- <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
- <1661> Evaluation of Plastic Packaging Systems And Their Materials of Construction With Respect to Their User Safety Impact

The purpose of the proposed revisions will be to provide an implementation period extension of the requirements specified in General Chapters <661.1> and <661.2>, which otherwise were to become applicable on May 1, 2020 through reference in General Chapter <659>; and to allow early adoption of the requirements in General Chapters <661.1> and <661.2> at any time during the implementation delay period. The proposed revisions will also be used to reformat and revise the extractable element approach, and to clarify content in <661.1>, <661.2> and <1661>.

The specific proposed revisions are as follows:

- Delay until December 1, 2025 the implementation of new requirements of General Chapters <661.1> and <661.2> as referenced in General Chapter <659>.
- To make General Chapter <661>, as referenced in General Chapter <659>, applicable until December 1, 2025.
- Clarify in General Chapter <659> that early adoption of the requirements of <661.1> and <661.2> is allowed by USP, and that packaging systems conforming to these requirements in advance of December 1, 2025 are considered by USP to be in conformance with the USP–NF.
- Reformat and clarify content in <661.1> and <661.2> to improve usability
- Revise the extractable element testing approach in <661.1> and <661.2>
- Revise <1661> to align with the changes that have occurred in <661.1> and <661.2>.

The proposed revisions are posted below and will be published as an In Process Revision (IPR) in *Pharmacopeial Forum* 45(2) [March–April 2019], with a pre-posting on the USP Website January 1, 2019. The comment period for this revision ends on May 31, 2019. In the absence of any adverse comments the proposed IPR is anticipated to become official on August 1, 2020.

- [<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](#)
- [<1661> Evaluation of Plastic Packaging Systems and Their Materials of Construction with Respect to Their User Safety Impact](#)

Should you have any questions, please contact Desmond G. Hunt, Scientific Liaison to the General Chapters–Packaging and Distribution Expert Committee (301–816–8341 or dgh@usp.org).

* This notice was updated on December 28, 2018 to add the links to the proposed revisions in advance of their publication in *PF* 45(2).