## <u>Change to General Chapters References to Preservation, Packaging, Storage and Labeling Section of</u> General Notices

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USP is alerting stakeholders that the reference to the Preservation, Packaging, Storage and Labeling section of the General Notices will change to General Chapter <659> Packaging and Storage Requirements in the following General Chapters:

- 1. <660> Containers—Glass
- 2. <661> Containers—Plastics
- 3. <671> Containers—Permeations
- 4. <729> Globules Size Distribution in Lipid Injectable Emulsion
- 5. <797> Pharmaceutical Compoundng—Nonsterile Preparations
- 6. <1079> Good Storage and Shipping Practices
- 7. <1146> Packaging Practices—Repackaging a Single Oral Drug Product into a Unit-Dose Container
- 8. <1160> Pharmaceutical Calculation in Prescription Compounding
- 9. <1177> Good Packaging Practice
- 10. <1178> Good Repackaging Practices

This change is considered to be an editorial change and will appear in these general chapters in *USP 36–NF 31*, with an official date of May 1, 2013.

## **Background**

In 2010, the Packaging, Storage and Distribution Expert Committee proposed, as new, General Chapter <659> Packaging and Storage

Requirements. The chapter took definitions pertaining to packaging and storage requirements from the Preservation, Packaging, Storage, and Labeling section in the General Notices (sections 10.10-10.30.100 and 10.50) and edited, added, and deleted definitions to reflect current industry terminology. The proposed new chapter was approved by the Expert Committee and became official May 1, 2012 in *USP 35–NF30*. Changing the above-listed chapters to refer to General Chapter <659> rather than the Preservation, Packaging, Storage and Labeling section of the General Notices will allow the updated definitions for packaging and storage included in General Chapter <659> to be utilized.

Proposed revisions to the General Notices will be published as an in-process revision in Pharmacopeial Forum (PF) 38(6) and reflect the movement of the packaging and storage requirements from the General Notices to General Chapter <659>. USP previously issued an Intent to Revise Notice for the General Notices that includes this proposal.

Should you have any questions regarding General Notices, please contact Mario Sindaco, Director, Compendial Affairs and Executive Secretariat (301-816-8246 or <a href="mailto:mys@usp.org">mys@usp.org</a>). For questions related to General Chapter <659>, contact Desmond Hunt, Ph.D., Senior Scientific Liaison to the General Chapters—Packaging Storage and Distribution Expert Committee (301-816-8341 or <a href="mailto:dgh@usp.org">dgh@usp.org</a>).