## General Chapter <795> Pharmaceutical Compounding—Nonsterlie Preparations

Type of Posting: Notice of Intent to Revise

Posting Date: 30-Mar-2018

Targeted Official Date: 01–Dec–2019

**Expert Committee:** Compounding 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 Compounding Expert Committee intends to revise General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations.

Major revisions of the General Chapter include:

- Reorganized existing chapter to improve clarity and to place key procedural information in boxes.
- Removed information on handling of hazardous drugs and added references to General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings.
- Expanded guidance for assigning beyond-use dates (BUD) for compounded nonsterile preparations (CNSP) in the absence of stability information.
- · Removed the existing categories of compounding.
- Defined personnel and facility requirements.

The proposed revision will be published in *Pharmacopeial Forum* 44(3) [May.–Jun. 2018] pursuant to section 7.02 of the Rules and Procedures. The comment period for this revision ends on July, 31, 2018. In the absence of any adverse comments the proposed Interim Revision Announcements will become official on Dec 1, 2019. To allow additional time for public review and comment, the proposed revisions are included below in advance of their publication in PF 44(3):

<795> Pharmaceutical Compounding—Nonsterile Preparations

Please use the <u>electronic form</u> to submit your comments. Comments should include corresponding section and line number to the proposed

| revisions to the General Chapter.                                                                                              |
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| Should you have any questions, please contact Jeanne Sun, Manager to the Compounding Expert Committee (CompoundingSL@usp.org). |
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