



Appeals Panel Decisions on USP <795>, <797>, and <825>

USP's Appeals Panel has issued final decisions on appeals to revisions to General Chapters [<795> *Pharmaceutical Compounding – Nonsterile Preparation*](#), [<797> *Pharmaceutical Compounding – Sterile Preparations*](#), and new [<825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*](#), which were published on June 1, 2019. USP remains committed to keeping stakeholders and the general public informed of the status of these standards.

Background

On June 1, 2019, USP published revisions to General Chapter <795> for nonsterile compounding and General Chapter <797> for sterile compounding, as well as a new General Chapter <825> for radiopharmaceutical compounding. After publication of the revised and new compounding standards, USP received appeals on certain provisions in <795>, <797>, and <825>. In accordance with [USP's Bylaws](#), the responsible Expert Committees considered the information raised in the appeals and issued decisions on the appeals. As part of the formal USP appeals process, four (4) stakeholders who submitted appeals to the compounding chapters requested further review by an appointed Appeals Panel.

Appeals Panel Decisions

After thoughtful deliberation and evaluation of the record and hearings from the appellants on January 21 and 22, 2020, the Appeals Panel made the following decisions on the appeals.

▶ **General Chapters <795> and <797>**

The Appeals Panel has granted the appeals to General Chapters <795> and <797> and is remanding the chapters to the Compounding Expert Committee (CMP EC) with the recommendation for further engagement on the issues raised concerning the beyond-use date provisions.

▶ **General Chapter <825>**

The Appeals Panel has denied the appeal to General Chapter <825> and encouraged the appellant to submit the narrower request presented at the hearing before the Panel to the Chemical Medicines Monograph 4 Expert Committee (CHM4 EC) as a request for revision.

Implications of Appeals Panel Decisions

▶ **General Chapters <795> and <797>**

The currently official chapters of [<795>](#) (last revised in 2014) and [<797>](#) (last revised in 2008) remain official.

The Appeals Panel did not determine that the chapters require revision but noted that the issues raised in the appeals warrant additional dialogue and consideration. It is the purview of the CMP EC to determine the appropriateness of future revisions to the chapters, if any.

Recognizing the public health impact of these standards, USP is committed to further stakeholder engagement through stakeholder forums, roundtables, and other avenues to gather more input on the issues raised in the appeals. USP and the



CMP EC are committed to moving forward in an open, transparent, and balanced manner as soon as practicable to enable the chapters to be finalized and implemented in a timely manner.

▶ General Chapter <825>

The responsible Expert Committee, CHM4 EC, may reinstate the official date of <825>. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. The CHM4 EC will announce an official date once it is determined.

Chapter <825> will be [informational and not compendially applicable](#). From a compendial standpoint, a USP general chapter numbered below <1000> becomes applicable and compendially required through reference in General Notices, a monograph, or another applicable general chapter numbered below <1000>. Since <825> is not referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>, <825> is an informational chapter unless otherwise required by a regulatory body.

With decisions on these appeals having been made and communicated, the Appeals Panel has concluded its service. The members of the Appeals Panel will maintain strict confidentiality in connection with their involvement in the adjudication of the appeals.

Any questions about these Chapters or the USP appeals process should be directed to USP Healthcare Quality & Safety staff at CompoundingSL@usp.org.

