

USP Appeals Panel issues decisions on compounding chapters

Rockville, MD, March 12, 2020 — After thoughtful deliberation and evaluation of the record and hearings from appellants on January 21 and 22, 2020, the USP Appeals Panel has completed deliberations and delivered its decisions on the second level of appeals to revised USP General Chapters [<795> *Pharmaceutical Compounding – Nonsterile Preparation*](#), [<797> *Pharmaceutical Compounding – Sterile Preparations*](#), and new [<825> *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*](#).

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). The Appeals Panel did not determine that the chapters require revision but noted that the beyond-use-date issues raised in the appeals warrant additional dialogue and consideration.

The currently official versions of <795> (last revised in 2014) and <797> (last revised in 2008) remain official as a result of the remand. Recognizing the public health impact of these standards, USP is committed to further stakeholder engagement through forums, roundtables, and other avenues to gather more input on the beyond-use-date 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.

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

Due to the denial of the appeal to <825>, the CHM4 EC may reinstate the official date of this new chapter. Based on USP's Bylaws, the Expert Committee must provide at least another six-month implementation period for this Chapter. USP will announce an official date once it is determined. At this time, General Chapter <825> will be informational unless otherwise required by a regulatory body.

With the appeals decisions having been made and communicated, the Appeals Panel has concluded its service. “These complex Panel-level appeals were a first in USP’s 200-year history, and we thank the Appeals Panel for their meticulous and thoughtful review of the appellants’ issues and concerns,” commented Jaap Venema, Ph.D., Executive Vice President & Chief Science Officer at USP. “We will continue to remain transparent and seek stakeholder input to create independent standards that help ensure the quality of medicines and patient safety.”

The members of the Appeals Panel will maintain strict confidentiality in connection with their involvement in the adjudication of the appeals. Any questions about the Compounding Chapters or the USP appeals process should be directed to Healthcare Quality & Safety staff at CompoundingSL@usp.org.

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people worldwide. For more information about USP, visit www.usp.org.

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