



December 21, 2021

Brenda Jensen, CPhT
Chairman, Compounding Expert Committee
U.S. Pharmacopeia
126 Twinbrook Parkway
Rockville, Maryland 20852

RE: Request for Extended Comment Period on Proposed USP <795> and <797> Beyond-Use Dates

Dear Chairman Jensen:

On behalf of the Alliance for Pharmacy Compounding, the American Pharmacists Association, and the National Community Pharmacists Association, **we write to ask that the Compounding Expert Committee move to extend the deadline for public comment on its proposed USP Chapter <795> and <797> revisions by three months, from the current January 31, 2022, deadline to an April 30, 2022, deadline.**

Collectively, our organizations represent pharmacists practicing in every pharmacy practice setting. The ability of many of those pharmacists to serve their patients will be affected by the beyond-use dating standards determined by your committee. Our organizations have been working to share USP's proposed revisions with our memberships and gather their thoughts about how these revisions would impact them, their patients, and prescribers. Many pharmacists and prescribers do not realize that their activities are considered compounding, and therefore, more education of those stakeholders is required before we can gather meaningful feedback on how these changes would impact patient care. Due to the time involved in these activities we believe an extension of the comment period is warranted.

Our specific reasons for this requested extension are two-fold:

1. To allow sufficient time for our organizations to assess and gather data for the committee on the real-world implications of the proposed beyond use dates (BUDs) on patient care and access, as well as pharmacy workflows; and
2. To allow us to orient and gather feedback from prescribers/providers about the potential implications of the proposed BUDs on their ability to care for their patients.

A comment period that spans the holiday season of late November through New Year's Day – as USP's comment period on the proposed BUDs does – creates challenges for capturing stakeholders' full attention. For that reason alone, we believe an extension is in order.

Thank you for your consideration. We will continue to assist USP and the committee in gathering input on and assessing the effects of your proposals. We would welcome your notification of a comment extension that extends an additional three months.

Please contact Scott Brunner at scott@a4pc.org if you have questions or need any additional information.

Sincerely,

Alliance For Pharmacy Compounding (APC)
American Pharmacists Association (APhA)
National Community Pharmacists Association (NCPA)