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REGULATORY UPDATES

USP <795> & <797>

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The road to publishing the revisions to USP General Chapters <795> and <797> has been a long one. Since their initial publication in June of 2019, USP has received several appeals on <795> and <797>. These appeals included potential harm to patients, unjustifiable burden on established businesses, and concerns regarding the proposed guidelines departing from scientific consensus.1 Though these reasons for appeal continue to be sources of concern, USP published revisions to <795> and <797> on November 1st, 2022, stating they are "to be official 01-Nov-2023".2,3

What does this mean for my practice?

Until November 1st, 2023, the current version of General Chapter <795>, which was last revised in 2014, will remain in effect. Similarly, the current version of General Chapter <797>, which was last revised in 2008, will also remain in effect until November 2023. It should be noted that while USP does create guidance documents for industry, they are not themselves a regulatory body. That said, many state regulators adopt USP guidelines into their rules and regulations. Some states may even adopt some or all of these new USP guidelines before November 1, 2023. As such, we encourage you to contact or closely follow communications from regulators (i.e., newsletters) in the states in which you are licensed.

What are the changes to beyond use dating (BUD) practices with new USP <795>?2

There are many changes from previous USP <795> in the updated guidelines. One area of concern to many compounders is beyond use dating for non-sterile compounded products. Included below is a comparison of current and updated BUDs. Of note, the updated guidelines do not divide aqueous dosage forms based on route of administration, but rather based on preservative status. This is consistent with a new emphasis on water activity (aw) and microbial growth that we see in updated guidelines. Updated guidelines reference specific aw values for determination on whether a particular preparation is aqueous or nonaqueous (for more information, see our blog post on water activity, linked below). Updated guidelines will also have more stringent requirements for BUD extension, including the requirement for stability indicating analytical methods, container-closure specific testing, and anti-microbial effectiveness testing per USP <51>, among other considerations.

Current USP <795> (since 2014)

BUD by Type of Formulation	
For Water-Containing Oral Formulations	The BUD is not later than 14 days when stored at controlled cold temperatures
For Water Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations	The BUD is not later than 30 days.
For Nonaqueous Formulations	The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier

Updated USP <795> (To be official Nov 1st, 2023)

BUD Limit by Type of Preparation in the Absence of a USP-NF Compounded Preparation Monograph or CNSP-Specific Stability Information (Table 4)	
Non-preserved aqueous dosage forms (a_w ≥0.60)	14 days refrigerated
Preserved aqueous dosage forms (a_w ≥0.60)	35 days controlled room temperature or refrigerated
Oral liquids (nonaqueous) (a_w < 0.60)	90 days controlled room temperature or refrigerator
Other nonaqueous dosage forms (a_w < 0.60)	180 days controlled room temperature or refrigerator

What does this mean for USP 800?4

USP's official statement on USP General Chapter <800> is that "USP General Chapter <800> is informational and not compendially applicable unless otherwise specified by regulators and enforcement bodies. For information on the scope, intended applicability, and implementation context for USP General Chapter <800>, see: https://www.usp.org/usp-800-context-for-implementation-fs.pdf." Information provided by USP suggests that USP <800> is intended to become applicable to compounding activities through reference in the updated USP <795> and <797> guidelines. Given this information, USP <800> would be considered official on the same date as USP <795> and <797> updated guidelines. Again, note that some state regulators may adopt all or portions of USP <800> before November 2023.

Where do I go to learn more?

USP will be offering Open Forum sessions regarding the changes to USP <795> and <797> on November 8th. These sessions will include presentations on the General Chapter revisions, as well as an opportunity to have questions addressed. Fagron encourages you to sign up for these free sessions at the link below! Fagron will also be releasing webinars regarding proposed changes in the coming months, as well as resource documents to make understanding the changes more easily digestible. Included below are links to materials Fagron has already posted regarding USP <795> and <797> revisions. More to come in the near future!

Available to all Fagron Customers: Water Activity: USP 795 Changes

Available to all FACTS Members: USP Proposes Substantial Revisions to Chapters <795> and <797>

Link to sign up for USP General Chapters <795> and <797> open forums: USP Virtual Open Forum Series: Revisions to Compounding General Chapters

Sources:

1. Allen L. Formal Appeals to United States Pharmacopeia Regarding USP Chapters M795>, <797>, and <825>: Part 1. IJPC. 2020; 24(2): 92.
2. United States Pharmacopeia and National Formulary. USP <795> Pharmaceutical Compounding – Nonsterile Preparations. Current DocID: GUID-98DCB48D-DC23-4A63-AD2E-01CA8979FB7E_5_en-US
3. United States Pharmacopeia and National Formulary. USP <797> Pharmaceutical Compounding – Sterile Preparations. Current DocID: GUID-A4CAAA8B-6F02-4AB8-8628-09E102CBD703_6_en-US
4. United States Pharmacopeia and National Formulary. USP <800> Hazardous Drugs- Handling in Healthcare Settings. Current DocID: GUID-5D76173F-5CB6-47B8-815E-7C275A916085_7_en-US

For further information or questions, please feel free to reach out to us by heading to www.fagronacademy.us!