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Alliance for Pharmacy Compounding

February 3, 2021

Dr. Gus Bassani
Chairman, USP Compounding Expert Committee <795> Subcommittee
U. S. Pharmacopeia
12601 Twinbrook Parkway
Rockville, Maryland 20852

Dear Chairman Bassani:

On behalf of the Alliance for Pharmacy Compounding, and as chair of APC's Beyond-Use Date Task Force, I wish to offer input that we believe can assist your subcommittee's work to determine proper beyond-use date standards for non-sterile compounded preparations.

As you may know, the Alliance for Pharmacy Compounding (formerly the International Academy of Compounding Pharmacists) is the voice for pharmacy compounding, representing thousands of pharmacists, technicians, students, researchers and suppliers. Compounding exists for patients and animals who are not served by traditional pharmaceutical manufacturers. We create custom medications that patients simply cannot get anywhere else. Every day, our members play a critical, often life-or-death role in patients' lives. They are a valued part of the health care team, creating essential treatments unavailable elsewhere for a range of issues, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, and many others.

APC and its members have a great interest, of course, in the updated USP <795> chapter that was published in June of 2019. Along with other stakeholders, we appealed the new <795> and <797> chapters developed by USP based on our grave concerns about the restrictions on beyond-use dates in those chapters, and we understand that the current work of your subcommittee is the result of the granting of our appeal in March of last year.

On behalf of APC's Beyond-Use Date Task Force, I wish to share our recommendations regarding default BUDs for nonsterile products in Chapter <795>. Our Task Force is also working on recommendations related to BUDs in Chapter <797>, and we will share those with the proper USP CEC subcommittee when they are completed.

As a general recommendation, we urge that your subcommittee base its recommendations to the full CEC on science and not on arbitrary dates. We understand the need for default dates that are applicable to the greatest number of compounds in order to make enforcement of those BUDs easier for regulators. However, as highly trained scientists, compounding pharmacists have the ability to use many different resources and techniques to apply appropriate BUDs to compounded nonsterile products.

Below is our proposed BUD chart for non-sterile preparations, as well as the justifications for our proposals. We recommend that if a pharmacy is willing to do a stability study for a particular compounded product (including container), that pharmacy should be allowed to use the BUD that the science justifies, and that it not be limited to a specified maximum date.

Default Beyond Use Dates for Solid and Preserved Liquid Dosage Forms/Formulations

Dosage Form or Formulation	**Proposed BUD**	**Justification (Scientific and Experiential)**
Electrolyte Solutions	180 days Refrig 120 days Rm Temp	USP Monographs
Antibiotic and Preservative Free Aqueous Solutions/Suspensions	14 Days Refrig	Commercial reconstituted oral antibiotic products.
Preserved Aqueous API Solutions/Suspensions	60 days Refrig 35 days Rm Temp	Based on USP Monographs and published studies. For less stable preparations, see below[2].
Preserved Aqueous API Semi-Solid Dosage Forms Intended to be Applied Topically or to Mucous Membranes	90 days Rm Temp	USP Monographs
Nonaqueous Solutions/Suspensions	6 months	USP Monographs and published studies[1]. For less stable preparations, see below[2].
Nonaqueous Solids	6 months	Based on published studies and experiential information.
Preserved Vehicles with no API	1 year if supported by USP <51> Antimicrobial Effectiveness Test	No API. Observe for physical and microbiological changes.

[1] *A published article with a BUD established using a validated stability-indicating analytical method can be used if the compounded preparation is the same as that in the study.*

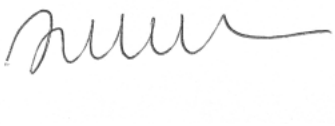
[2] *Exceptions to these default BUDS are to be noted and published as they occur. (Comment: It is not reasonable to establish a BUD based on the most troublesome preparations, but rather to use those as exceptions to the defaults.) Example Exceptions that do not fit the above: Baclofen (See USP Monograph), Hydralazine (See USP Monograph).*

We also request that USP clarify its stance on using published stability studies in order to use its BUDs. There is confusion as to how to interpret these studies and how to apply them. If a study, for example, is for a compounded estriol vaginal cream, may the compounding pharmacist use any manufacturer's Estriol USP, provided he or she applies the recommended BUD for the specified base/vehicle?

We appreciate USP's commitment to consider input from all stakeholders regarding the revisions to Chapter <795> related to default BUDs. **We would welcome the opportunity to discuss our**

recommendations with your subcommittee or, if appropriate, with the full Compounding Expert Committee. If a conversation is desired, please contact APC CEO Scott Brunner at scott@a4pc.org.

Sincerely,



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C: APC Board of Directors
APC Beyond-Use Date Task Force