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Re: **41(5)** The General Chapters—The Dosage Forms Expert Committee proposed revisions to ⟨1⟩, ⟨2⟩, ⟨3⟩, ⟨4⟩, ⟨5⟩, and ⟨771⟩.
Correspondence Numbers—C161336; C128347; C160057; C160868; C14832; C159266; C131378; C160869

Dear Liaisons:

On behalf of the Consumer Healthcare Products Association (CHPA), a 134 year-old trade association representing the nation's leading over-the-counter (OTC) medicine and nutritional supplement manufacturers, I'd like to thank you for the opportunity to comment on the proposed revisions to the General Chapters ⟨1⟩, ⟨2⟩, ⟨3⟩, ⟨4⟩, ⟨5⟩, and ⟨771⟩ published in PF 41(5).

CHPA supports improving the compendial test methods and establishing product standards for the variety of dosage forms addressed in these chapters which can provide an additional measure of safety for OTC products. CHPA generally supports the improvements included in the latest chapter revisions but is concerned with the proposals to include specific tests that may or may not be required. CHPA believes that in order to clarify the applicability of these chapters USP consider that tests that are not required be moved into chapters numbered greater than <1000> (for information only).

CHPA believes that the entire "Ophthalmic Route" section of <4> should be removed and incorporated into <771> since much of it is redundant. We would also note that Chapter <4> references <771> as *Ophthalmic Ointments*, and not as the proposed <771> *Ophthalmic Products* which may result in a compliance issue depending on implementation timing.

The Dosage Forms Expert Committee proposed revisions to ⟨1⟩, ⟨2⟩, ⟨3⟩, ⟨4⟩, ⟨5⟩, and ⟨771⟩, in PF 41(5).

In order to clarify the applicability of these chapters we suggest that USP consider that tests which are not required be moved into chapters numbered greater than <1000> (for information only). Not only will it add clarity for manufacturers developing standards, FDA for surveillance and compliance activities, but for international requirements as well. Many countries outside of the US rely on USP standards and can and do require that all listed tests be performed. Adding to lack of clarity, the proposed chapters <1>, <2>, <3>, and <4> use different language presumably to indicate the same intentions:

<1> In addition to the Universal Tests listed above, the following Specific Tests may be considered on a case-by-case basis and, when appropriate, are referenced in the USP–NF monograph.

<2> In addition to the Universal Tests described above, the following specific tests for tablets should be considered, depending upon the nature of the drug substance and formulation.

<3> In addition to the Universal Tests listed previously, the following Specific Tests should be considered on a case-by-case basis:

<4> In addition to the generally necessary product quality tests already discussed, the dosage form may require specific quality tests that are common across routes of administration.

Clarification is needed for directives and/or acceptance criteria listed in <3> for Uniformity of Active Ingredients:

It is possible to move directly to Step 3 testing from Step 1 if a single result is greater than 5% beyond the assay specification range (and less than 15%). The acceptance criteria are based on a total number of units tested that includes the Step 2 testing, and the directive provided assumes two units were tested at Step 2. USP should allow for testing 7 or 9 additional containers, as appropriate.

Clarification is needed for Product Quality Tests section "Microbial Limits" in <3>

Update the header to "Microbiological Examination of Nonsterile Products" to be consistent with corresponding USP Chapter <1111> title. Acceptance criteria statement should read "Acceptance criteria for nonsterile pharmaceutical products are given in Microbiological Examination of Nonsterile Products: Acceptance

Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use <1111>".

Clarification is needed for Product Quality Tests section "Antimicrobial Preservative Content" in <3>

Update the header to "Antimicrobial Effectiveness Testing" to be consistent with corresponding USP chapter <51> title. The first sentence should reference application of AET for "aqueous-based, multiple-dose dosage forms".

The above updates of both sections "Microbiological Examination of Nonsterile Products" and "Antimicrobial Effectiveness Testing" should be harmonized to the appropriate content sections in general chapters <2>, <4>, and <5>.

CHPA appreciates the opportunity to comment on the proposed General Chapters ⟨1⟩, ⟨2⟩, ⟨3⟩, ⟨4⟩, ⟨5⟩, and ⟨771⟩ published in PF 41(5). I am happy to speak with you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,

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