Via Email (derekshaffer@quinnemanuel.com)

November 20, 2019

Dear Mr. Shaffer:

We write in response to your November 7 letter and in further response to your September 13 letter concerning the Coalition's further appeal of the revisions of beyond-use date standards in General Chapters <795> and <797>. We have the following comments in this regard:

Hearing Dates. USP's Appeals Panel would like to offer the opportunity for in-person hearings on Tuesday, January 21 and Wednesday, January 22, 2020. It is our hope that with this much advance notice, the Coalition will be able to participate on one of those dates. Please advise at your earliest convenience about the Coalition's availability. We will schedule hearings on a first-come basis, as we are trying to accommodate a number of different appellants. If the Coalition cannot participate in person on either January 21 or 22, we will offer a teleconference/WebEx hearing on another date in January. We intend to conclude the hearing phase by the end of January.

Hearing Procedures. USP is establishing procedures for the hearing and anticipates that they will include the following features:

Time Allotted for Each Appellant. After considering your feedback and that of other appellants, the Appeals Panel will offer each appellant the opportunity to make a two-hour presentation with 30 minutes for the Appeals Panel to ask follow-up questions. Please advise when you confirm your hearing date availability whether the Coalition requests that some or all of its hearing be treated as confidential and conducted in closed session. We intend to treat the hearings as open meetings unless we are notified otherwise.

Hearing Record. USP intends to retain a court reporter to produce a full transcript. USP will make the transcript available to each appellant.

Composition of the Appeals Panel. Consistent with the USP Bylaws, the Appeals Panel is constituted specifically for the appeals concerning the proposed revisions to the compounding chapters. None of the members of the Appeals Panel served on the Expert Committee that developed and approved the standards under appeal. The Appeals Panel was selected to include relevant scientific and USP process expertise. It will be well-positioned to evaluate information and arguments presented by the Coalition and to assess the presentation in light of the development and approval of the provisions being challenged.

The members of the Appeals Panel are:

Jesse L. Goodman, M.D., M.P.H., President, USP Convention
Mary Foster, Pharm.D., Council of Experts
Dennis K.J. Gorecki, B.S.P., Ph.D., Council of Experts
Amy J. Karren, B.Sc., Council of Experts
Timothy R. Franson, B.S.Pharm., M.D., Board of Trustees
Marilyn K. Speedie, Ph.D., Board of Trustees
Thomas R. Temple, B.S.Pharm., M.S., FAPhA, Board of Trustees

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Scope of the Hearing. The hearing is intended to be your opportunity to present. The Panel will reserve time at the end to ask clarifying questions. USP does not intend to make any members of staff or volunteer bodies (e.g., Expert Committee members) available to serve as witnesses for the hearing. The Coalition is free to present any evidence that it feels is relevant to further review of the Expert Committee's decision on the appeal, which may include scientific evidence, data, and expert witness testimony. Further, the Coalition is free to present on information made available after its submission of the original appeal. In short, it is our hope that the Coalition will utilize the 2 hours of hearing presentation time to share any scientific and other information that it feels warrants further review by the Appeals Panel.

Under Section 7.06(a) of USP's Rules and Procedures of the Council of Experts, new or revised documentary standards "must be voted on and approved by the responsible Expert Committee." Thus, the Appeals Panel is not authorized to revise the text or substance of the standards under appeal. For this reason, after due deliberation the Appeals Panel will either: (1) deny the appeals, resulting in the standards approved by the Expert Committee becoming official; or (2) grant one or more of the appeals, resulting in a remand of the standards to the Expert Committee for further evaluation, stakeholder engagement, and/or revisions.

Conformance Deadline. Consistent with Article VII, Section 7.e. of the Bylaws, we confirm that the date for required conformance with any new or revised standard will not be less than six months after the Appeals Panel's last decision resolving the appeals.

Inquiry concerning Conflicts of Interest. The Coalition requests information concerning conflicts of interest for certain Expert Committee members, as referenced in a footnote of our August 16 response to the Coalition's first-level appeal. Under Section 2 of the Rules and Procedures of the Council of Experts, USP is required to maintain confidentiality relating to the conflict-of-interest disclosures of its Expert Committee and Expert Panel members, who themselves have obligations to maintain confidentiality of information gained in the course of their participation in USP activities.

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We look forward to hearing from you regarding the Coalition's availability for a hearing in January. Please let us know if you have any questions about the above, and we would be glad to schedule a phone conversation to discuss further.

Kind regards,



Mario Sindaco
Vice President, Science—Operations and Executive Secretariat, Council of Experts