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September 13, 2019

Mario Sindaco
Vice President, Science—Operations and
Executive Secretariat
United States Pharmacopeia
12601 Twinbrook Parkway
Rockville, MD 20852-1790
execsec@usp.org

Re: Notice of Further Appeal of Revisions of Beyond-Use Date Standards in General Chapters <795> and <797>

Dear Mr. Sindaco:

I write on behalf of International Academy of Compounding Pharmacists, Innovation Compounding, and Wedgewood Village Pharmacy (collectively, “the Coalition”) in response to your letter dated August 16, 2019 denying the Coalition’s appeal of the United States Pharmacopeia’s (“USP”) proposed revisions to USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations and to USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations. The Coalition respectfully disagrees with USP’s denial of its appeal and is therefore further appealing pursuant to Article VII, Section 7(c) of the Bylaws of the United States Pharmacopeia Convention.

The Coalition is asking to be afforded a full and fair hearing that will entail meaningful presentation and consideration of the merits of the Coalition’s appeal (quite different from the summary dismissal reflected in USP’s August 16, 2019 letter). Notably, information that has come to light only subsequent to the Coalition’s initiation of the appeal—particularly in response to the Coalition’s Information Requests—indicates that USP has been secretly deliberating for years over the revisions at issue and conferring extensively with FDA about them, while withholding key inputs from public scrutiny and testing. In light of these revelations, it seems all the more imperative that the Coalition be afforded a forum and means for making its case and conveying its concerns to USP.

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The Coalition intends to follow-up under separate cover regarding the relevant procedures, particularly as to timing and other particulars for the hearing. In the meantime, we ask that USP kindly confirm that the date by which conformance with the new standards is purportedly required (*i.e.* December 1, 2019) shall remain postponed while the Coalition's appeal is pending. *See* Article VII, Section 7 of the Bylaws of the United States Pharmacopeia Convention. Similarly please also confirm that if the Coalition's appeal is denied, the date by which conformance with the new standards will be reestablished by USP so that the period allowed for implementation "is not less than that provided for upon original publication of the standard." To be concrete, our understanding is that, per the express terms of USP's Bylaws, the new standards cannot take effect until (at the earliest) six months after USP renders its post-hearing decision resolving the Coalition's appeal. If USP's view differs, it owes it to the Coalition and all other affected entities to announce as much at the earliest opportunity.

Thank you for your prompt attention to this matter. We look forward to your response and to arranging details about how and when the forthcoming hearing will proceed.

Very truly yours,



Derek L. Shaffer