

December 30, 2022

By Electronic Mail

Executive Secretariat
The United States Pharmacopoeial Convention
12601 Twinbrook Parkway
Rockville, Maryland 20852
compoundingSL@usp.org

Re: Request for an Appeal and Extension of Time Related Thereto,
Final Revised General Compounding Chapter <797> Published on November 1, 2022

Dear Sir or Madam:

Pursuant to article VII, section 8 of the 2020-2025 USP Bylaws and section 9.08 of the Rules and Procedures of the 2020-2025 Council of Experts (Rules), the Alliance for Pharmacy Compounding (APC) requests an appeal of the final revised general compounding chapter <797> published by The United States Pharmacopoeial Convention (USP) on November 1, 2022 (the 2022 Revisions).

Furthermore, because of the unprecedented and ongoing weather-related travel disruptions occurring throughout the United States, APC respectfully requests a 30-day extension of time in which to submit a detailed statement of grounds with supporting information under section 9.08(a) of the Rules. USP has announced that the 2022 Revisions will not become official until November 1, 2023. Therefore, the granting of a 30-day extension of time to APC—which would move the submission deadline to Monday, January 30, 2023, from the present deadline of Saturday, December 31, 2022—will not prejudice USP and would instead permit USP to give thoughtful consideration to APC's grounds for its appeal. Those grounds will be narrowly tailored, process-based, and designed to ensure that the 2022 Revisions do not unintentionally cause harm to the public.

Please direct any correspondence on this matter to me at scott@a4pc.org.

Sincerely,



Scott Brunner, CAE
Chief Executive Officer

cc: Ronald T. Piervincenzi, PhD
Chief Executive Officer and Chairperson, Council of Experts
The United States Pharmacopoeial Convention

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