Maria Serpa, Chair Enforcement and Compounding Committee California Board of Pharmacy 2720 Gateway Oaks Dr, Ste 100 Sacramento, CA 95833

Re: Proposed Changes to Regulations Related to Pharmaceutical Compounding of Nonsterile Preparations

Dear Chair Serpa,

February 10, 2023

The California Pharmacists Association (CPhA) appreciates the discussion and work of the Enforcement and Compounding Committee Meeting in relation to the regulations related to pharmaceutical compounding of nonsterile preparations, specifically with the recent USP 795 recommendations on flavoring agents. CPhA writes to encourage the Board of Pharmacy to evaluate the implementation timeline of the USP 795 recommendations and to provide direct communication to pharmacies of the proper documentation requirements and enforcement guidance. We also request that the Board inspectors not begin to review compliance any earlier than November 1, 2023. This will allow pharmacists the necessary time to implement USP 795 guidelines.

As the largest pharmacy association in the state representing all areas of pharmacy practice, we recognize firsthand how important it is for children to take their medicines. The ability to alter the taste of medication increases patient adherence and plays an important role in our patient's health. Flavoring can be the difference between children taking their medicine or not, as is the case of numerous real-life examples of children with long-term conditions like epilepsy or autism, or children struggling to get over serious infections. In short, children, parents, pediatricians, and pharmacists all understand how important flavoring is to ensure that children take their prescribed medication as directed by their pediatricians and clinicians.

We appreciate the opportunity to comment and provide feedback to the Board on ensuring patients in the state continue to receive optimal pharmacists delivered care. Should you have any questions about this recommendation, please feel free to contact me at rvaidya@cpha.com.

Founded in 1869, the California Pharmacists Association (CPhA) is the largest statewide association representing the pharmacy profession in all practice settings. Our mission is to advance the practice of pharmacy for the promotion of health.

Thank you for your consideration.

Sincerely,

Rajan Vaidya, PharmD

Vice President, Practice & Professional Development