APhA
American Pharmacists Association

August 25, 2023

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2015-P-4131: Citizen Petition to US Food and Drug Administration Requesting the Removal of Oral Phenylephrine from the Final Monograph for OTC Nasal Decongestant Drug Products

Re: Docket No. FDA-2023-N-2653: Nonprescription Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

Submitted via https://www.regulations.gov/ for Docket No. FDA-2015-P-4131 & Docket No. FDA-2023-N-2653

Dear FDA Staff:

The American Pharmacists Association (APhA) writes in support of the action requested in the University of Florida's *Citizen Petition to US Food and Drug Administration Requesting the Removal of Oral Phenylephrine from the Final Monograph for OTC Nasal Decongestant Drug Products*, which was filed on November 4, 2015, with subsequent supplemental information (Docket FDA-2015-P-4131). APhA supports this petition's request to remove oral phenylephrine from the Final Monograph for over the counter (OTC) nasal decongestant products.

APhA is the only organization advancing the entire pharmacy profession. APhA represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

APhA represents our nation's pharmacists, who have tremendous experience with OTC oral phenylephrine products. They often receive feedback from patients who are seeking relief for nasal congestion, relying on claims that oral phenylephrine products will relieve their symptoms. These patients often complain of the ineffectiveness and lack of nasal congestion relief from oral phenylephrine products.

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APhA's Academy of Pharmaceutical Research and Science (APhA-APRS) members practice in academia, industry, and clinical settings focusing on the discovery, dissemination and application of basic and clinical sciences and research to improve patient health outcomes. APhA's member scientists in APhA-APRS have reviewed the information submitted in the citizen's petition and agrees with the totality of the evidence presented to support APhA's position.

Furthermore, the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020, included provisions that modified the way OTC monograph drugs are regulated. Specifically, the CARES Act replaced the standard rulemaking process with an administrative order process for issuing, revising, and amending OTC monographs. This process allows FDA to review nonprescription drugs, like oral phenylephrine, and remove nonprescription drug products that do not meet the legal standard for OTC use.

Conclusion

APhA requests that the FDA Nonprescription Drugs Advisory Committee consider APhA's views and position in the upcoming meeting on September 11-12, 2023, to discuss new data regarding the 'Generally Recognized as Safe and Effective' (GRASE) status of oral phenylephrine as a nasal decongestant that has become available since FDA last examined the issue in December 2007.

Based on the CARES Act provisions and a lack of data demonstrating the efficacy of oral phenylephrine as an OTC nasal decongestant, APhA supports removal oral phenylephrine from the Final Monograph for OTC nasal decongestant products. If you have any questions, please contact Heather Boyd, Director, Health Policy at hboyd@aphanet.org.

Sincerely,

Ilisa BG Bernstein

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice & Government Affairs