



September 8, 2023

To: Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Nonprescription Drugs Advisory Committee (NDAC); Notice of Meeting; Establishment of a Public Docket; Request for Comments (Sept. 11-12, 2023); [Docket No. FDA-2023-N-2653]

Dear FDA staff and NDAC Members:

On behalf of pharmacists practicing with older adults and the medically complex residing in assisted living, skilled nursing and in community settings, we strongly encourage you to continue recognizing phenylephrine (PE) as a safe and effective decongestant.

Founded in 1969, the [American Society of Consultant Pharmacists \(ASCP\)](#) is a professional membership association that represents senior care and consultant pharmacists, long term care pharmacies, health care professionals, and students serving the unique medication needs of older adults. ASCP is an international organization with members located in all 50 states, Puerto Rico, and 12 countries. The society's mission is to promote healthy aging by empowering pharmacists with education, resources, and innovative opportunities.

The [Alliance for Aging Research](#) is the leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. The Alliance believes advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term.

Access to PE is Beneficial for Public Health

PE's efficacy as an oral decongestant has been a subject of debate and further research. It has been recognized as a safe and effective temporary decongestant by the FDA for decades and

only recently has its efficacy been called into question. Regardless of the recent studies, its availability under the OTC Monograph has benefited public health and the entire U.S. healthcare system for some time. Working with aging individuals, ASCP and the Alliance recognize that every older adult is unique, and quite often, both clinicians and patients want accessible options to select mild or moderate self-treatment for their mild or moderate nasal congestion. OTC medicines containing oral PE deliver recognized benefits for the people who choose it.

Oral PE is the only OTC decongestant available without purchase restrictions, meaning that decreased access to this ingredient would have consequences for individuals and healthcare providers. Many individuals practice self-care and choose treatments for their symptoms at all hours and in all areas of the country, rural and urban. Equitable access to trusted, over-the-counter remedies is about removing barriers and preserving and expanding choice and availability. Without oral PE, consumers' ability to seek relief by self-treating their own mild to moderate symptoms would be significantly restricted. Furthermore, many would unnecessarily seek medical care from doctors, pharmacists, or clinics, placing increased burdens and costs on the healthcare system.

The other OTC oral decongestant, pseudoephedrine (PSE), is only available with access restrictions such as: needing to present an ID and sign a logbook. PSE is not available outside of pharmacies and even within big box pharmacies like grocery stores and other large format retail stores, it is not available outside of the pharmacy's hours. Oral PSE is subject to interstate commerce and the Control Methamphetamine Epidemic Act (CMEA), and it is subject to additional restrictions that may be imposed by states. Therefore, it may not be available to all consumers, depending upon their location. Further, consumers who report that they experience the efficacy and benefits of PE and who do not want other forms of decongestants will be frustrated if it is no longer available. Consumers will be forced to switch to other treatments, not necessarily specific to congestion, that have their own risks, benefits, and limitations.

Additionally, decongestant nasal sprays, while beneficial for some, are not recommended for individuals on certain oral medications, as well as prescription inhalers and/or nasal sprays. It is also not available in the many popular cold, flu, and sinus combination products that oral PE is, requiring consumers to make multi-purchases and use products that could make self-treatment for congestion with other symptoms even more challenging.

We applaud the FDA for emphasizing the importance of patient-reported outcomes, patient-focused-drug development, patient-centered decision-making, and patient engagement when making regulations. The FDA has stated that it looks to patients to understand how they describe their health status. The FDA also recognizes patients as "experts in living with their disease or condition," and the agency plays a central role in ensuring what matters to patients is factored into the regulatory decision-making process.

Sales data and a recent national survey suggest patients see effective and positive outcomes from self-care with OTC medicines containing PE. Sales data over the past year show that half of all U.S. households have purchased an OTC product with oral PE, and nearly 7-out-of-10 (68%)

of them have repurchased these medicines. In a national survey, 83% of adults reported outcomes including PE “helps relieve my nasal congestion,” even more so (86%) among people ages 65 and older. They also reported that PE helps them “get through the day because it relieves my nasal congestion,” (66% for all adults and 71% for those ages 50 and older). These are clear outcomes reported by patients that PE works and that using PE results in real-world clinical benefits.

PE is an Important, Accessible Self-Care Option

American adults rely on oral PE because they recognize its efficacy as a nasal decongestant and experience physical and personal benefits of oral PE when they use it. Beneficiaries and the healthcare system would experience additional burden if oral PE were not an available OTC, leaving only the more restrictive PSE as the only option. This is especially true among people ages 50+ and people living in rural communities.

Finally, the initial stated goal of the FDA regarding OTC medications is safety. There are many efficacy questions around certain herbal and vitamin supplements, and other currently available OTC medications, which may carry much higher risks than PE. Removing PE from market based on debatable and incomplete science regarding efficacy, sound safety evidence and without patient reported input makes the issue challenging to move forward.

Therefore, on behalf of Americans who rely on medicines containing oral PE for self-care, we strongly encourage you to continue recognizing PE as an available OTC decongestant.

Respectfully,

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