



December 4, 2023

Submitted via www.regulations.gov

Scott A. Brinks
Section Chief
Regulatory Drafting and Policy Support Section, Diversion Control Division,
Drug Enforcement Administration, Department of Justice
8701 Morrissette Drive
Springfield, VA 22152

Re: Proposed Aggregate Production Quotas for Schedule I and II Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine and Phenylpropanolamine for 2024. Docket No. DEA-1228P.

Dear Mr. Brinks:

On behalf of the Asthma and Allergy Foundation of America (AAFA), the leading patient organization advocating for people with asthma and allergies, and the oldest asthma and allergy patient group in the world, I am writing in response to the proposed aggregate production quotas for schedule I and II controlled substances. Common cold and allergy medicines that contain pseudoephedrine (PSE) are vital to patients with allergies and asthma. We have become aware that DEA may lower the quota amount for these important medicines and we request that DEA does not lower the quota amount for 2024.

Since 2011, AAFA has partnered with the Consumer Healthcare Products Association (CHPA) and other stakeholders to understand the PSE needs of the over 100 million Americans with allergies and asthma and to advocate for appropriate access to PSE.

For the past 20 years, AAFA has published our [Allergy Capitals in America Report](#)¹ which identifies the most challenging cities for seasonal allergies in the top 100

¹ Asthma and Allergy Foundation of America, (2023). 2023 Allergy Capitals. Retrieved from allergycapitals.com.



metropolitan areas in the continental United States. Notably, seasonal allergies have worsened since our first report in 2003. Seasonal allergic rhinitis, also known as “hay fever,” impacts 80.3 million people in the U.S., including 66.4 million adults and 13.9 million children.^{2,3} Allergic sensitivity to airborne pollen from trees, grasses, or weeds causes allergy symptoms. There is no cure for allergies, but allergies can be managed with prevention and treatment. Part of that treatment often includes medicines that combine an antihistamine with a decongestant like PSE.

Unfortunately, as detailed in our [Allergy Capitals](#) report, allergy seasons are only getting worse year over year due to climate change. Warmer temperatures and increased levels of CO₂ lead to longer growing seasons that change flowering time and increase pollen. Research shows pollen seasons now start 20 days earlier, and last 10 days longer, compared to 30 years ago.^{4,5}

Asthma also impacts over 27 million people in the U.S.^{6,7} and allergic asthma—where symptoms are triggered by allergens—is the most common type of asthma. Respiratory illnesses like the flu and common cold are also triggers for asthma exacerbations. Cold and allergy medicines containing PSE can be an important part of managing these triggers for our patient population.

² Ng, A.E. & Boersma, P. (2023). NCHS Data Brief, no 460: Diagnosed allergic conditions in adults: United States, 2021. National Center for Health Statistics. <https://dx.doi.org/10.15620/cdc:122809>

³ Zablotsky, B., Black, L.I., & Akinbami, L.J. (2023). NCHS Data Brief, no 459: Diagnosed allergic conditions in children aged 0–17 years: United States, 2021. National Center for Health Statistics. <https://dx.doi.org/10.15620/cdc:123250>

⁴ Anderegg, W. R. L., Abatzoglou, J. T., Anderegg, L. D. L., Bielory, L., Kinney, P. L., & Ziska, L. (2021). Anthropogenic climate change is worsening North American pollen seasons. *Proceedings of the National Academy of Sciences*, 118(7), e2013284118. <https://doi.org/10.1073/pnas.2013284118>

⁵ Climate Central. (2023). Seasonal allergies: pollen and mold. https://assets.ctfassets.net/cxgxcgstp8r5d/6HEq6ZLb0QpvXxScvaM7sc/ae3024a9c4f2bccdd9b563d09b1bd07c3/FINALSeasonal_allergies_pollen_and_mold_2023__EN_.pdf

⁶ National Center for Health Statistics. (2023). *2022 NHIS Adult Summary Health Statistics*. U.S. Department of Health and Human Services. <https://data.cdc.gov/d/25m4-6qqq>.

⁷ National Center for Health Statistics. (2023). *2022 NHIS Child Summary Health Statistics*. U.S. Department of Health and Human Services. <https://data.cdc.gov/d/wxz7-ekz9>



Asthma and Allergy
Foundation of America

Considering the worsening allergy seasons and trends of respiratory illness in the U.S., demand for cold and allergy medicines containing PSE are only poised to rise and we encourage DEA to not lower the PSE quota amount for 2024.

Please feel free to contact me directly if you have any questions or would like to discuss further.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America