



Asthma and Allergy
Foundation of America

April 27, 2023

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.
Submitted via regulations.gov

Re: Docket No. FDA-2023-N-0984 for “Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.”

Dear Committee Members,

I am writing to you on behalf of the Asthma and Allergy Foundation of America (AAFA), to comment on the Advisory Committee’s consideration of a new drug application (NDA) 214697, for epinephrine nasal spray, submitted by ARS Pharmaceuticals Inc., for the proposed indication of emergency treatment of allergic reactions (Type I) including anaphylaxis in adults and children \geq 30 kilograms.

AAFA, a not-for-profit organization founded in 1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. AAFA is dedicated to saving lives and reducing the burden of disease for people with asthma and allergic diseases through support, education, advocacy and research.

As you review information on the drug, AAFA encourages you to take into consideration the importance of maximizing epinephrine access and use among people living with allergies. In the U.S., food allergies impact 16 million adults and 4 million children. As you know, for people living with allergies, exposures to food, as well as beestings, latex, or other allergens, can trigger a severe reaction called anaphylaxis. If not treated promptly with epinephrine – the *only* treatment option that can reverse life-threatening symptoms– anaphylaxis can lead to death.



AAFA strongly supports policies that ensure that epinephrine is available to as many people, in as many places, as necessary to reverse severe allergic reactions and prevent allergy-related deaths. Currently, all available versions of epinephrine are injectable. Auto-injectors require minimal training, and we encourage all patients and caregivers to carry and use them. However, a nasal version – if found to be both safe and effective – would create another option for individuals and families with severe allergies. In addition, teachers and other staff who care for children with food allergies might feel more comfortable administering nasal epinephrine in an emergency.

Discomfort with needles, even for a lifesaving medication, is not theoretical. In our 2019 series of reports, [My Life with Food Allergies](#), we included results of a survey of over 1,200 parents of children with food allergies. Alarming, of the 1,095 parents who reported that their child had ever had a severe reaction, 72% said that for at least one severe reaction, epinephrine was not administered. Of those parents, 12% stated that their or their children’s “fear of the auto-injector (the device and/or needle)” was a reason for non-administration.

Interestingly, FDA’s approval of Narcan nasal spray in 2015 reflected an analogous expansion of options for the reversal of opioid overdose. In announcing the approval, [FDA noted](#):

Until this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector. Many first responders and primary caregivers, however, feel a nasal spray formulation of naloxone is easier to deliver, and eliminates the risk of a contaminated needle stick.

We are hopeful that people with allergies, as well as caregivers and first responders, will similarly find nasal epinephrine – if approved – to be a welcome option.

Access to, and use of, epinephrine is a multifaceted issue, with cost, regular medical care, and patient education as important factors. But fear of needles is real, and a



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modality that could make a subset of people more comfortable using an epinephrine device would be an important step for people with severe allergies.

Thank you very much for your time and attention. I look forward to presenting testimony at the Committee meeting next month, and to hearing the members' review of this potential new tool.

Sincerely,

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