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Via: <https://www.regulations.gov/document/FDA-2023-N-0984-0001>

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

On behalf of the over 32 million (1 in 10) Americans who suffer from life-threatening food allergies, and the 85 million (1 in 4 households) that are directly and indirectly affected by food allergies and/or intolerances to one of the top nine food allergens, the undersigned members of the [Food Allergy Collaborative](#) and additional supporting organizations appreciate the opportunity to submit the following comments on Docket No. FDA-2023-N-0984 for Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments for epinephrine nasal spray for the treatment of allergic reactions (type I) including anaphylaxis from ARS Pharmaceuticals, Inc.

Launched in 2019, the Food Allergy Collaborative is an alliance of advocacy organizations, those living with food allergies, and industry partners who are uniting to advance effective, patient-centered initiatives in food allergy awareness, research, and care. Our vision is to create lasting, system-wide change for the food allergy community. Bringing everyone to the table ensures that we can collectively identify issues in food allergy and create a shared vision to solve them. Together, we can coordinate our efforts to maximize impact.

Members of the Food Allergy Collaborative and other supporting organizations applaud FDA for convening a virtual meeting on May 11 of its Pulmonary-Allergy Drugs Advisory Committee to discuss 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, that has been assigned a Prescription Drug User Fee Act (PDUFA) target action date by mid-2023. The option for needle-free options is critically needed as the only currently available option for treatment for allergic reactions and anaphylaxis is intramuscularly administered epinephrine via an autoinjector. This was underscored as one of the priority themes in the recent [Voice of the Patient Report: Food Allergies](#) from the September 2021 Externally-led Patient Focused Drug Development (EL-PFDD) meeting supported by members of the Food Allergy Collaborative. As highlighted in the Report, we heard at the meeting:

*I'd love to see EpiPen be available without a needle, said one participant who has trained hundreds of lunch volunteers on how to use it. You're in emergency mode, and there is a little bit of fear about using an auto-injector that has a needle.*

Audience polling during the EL-PFDD meeting found that the most common issue posed by carrying epinephrine auto-injectors included inconvenience or difficulty of carrying due to size and fear of the

needle. Moreover, a recent Food Allergy Collaborative general population survey shows that nearly half of adults with food allergies do not carry epinephrine regularly (manuscript under development). Almost 10 percent of those who didn't have epinephrine cited it was due to fear of the device or medication.

We note that to date, the FDA docket for this Advisory Committee meeting has received over 525 comments to the FDA docket for this Advisory Committee meeting. The majority of submissions to the docket are testimonials from those with food allergy and their caregivers expressing support of needle-free epinephrine nasal spray.

The Food Allergy Collaborative and supporting organizations note that needle-free epinephrine nasal spray will reduce fear among those who need to deliver epinephrine as well as reduce injury from use of the traditional epinephrine autoinjector, and positively impact quality of life for many within the food allergy community. Innovative needle-free epinephrine delivery systems, such as via nasal spray will decrease barriers, increase trust and confidence of others to deliver this life-saving medication, and allow children to self-carry epinephrine earlier in childhood. Further, nasal antihistamine sprays are commonly used with children without fear and anxiety. The fear of and occurrence of bent or broken needles is real. We have received reports of injuries up to the needle causing a cut in the skin of the thigh that required multiple stitches and a resulting lifetime scar.

Needle-free epinephrine nasal spray is not only a critical innovation to use by those with food allergies who need to administer epinephrine. We believe that this innovation is critically needed in elementary and secondary schools, institutions of higher education, restaurants and institutional food service, hospitals, long-term care facilities, prisons, and all modes of transportation. Airlines are a top priority where needle-free epinephrine nasal spray will be most effective, particularly for those with severe peanut and tree nut allergies. While airlines include epinephrine vials in their emergency medical kits that require a medical professional to administer, epinephrine nasal spray would provide a safe, easy alternative for airlines to use as well as for customers to bring on-board. Its convenient size and ease of administration may encourage more food service operations to have nasal epinephrine on hand for use when a food allergy reaction occurs. Finally, fear of the needle can lead to delays in the administration of epinephrine as mentioned during the EL-PFDD meeting. Delays are known to increase negative outcomes. By reducing fear and hesitation, nasal epinephrine may increase positive outcomes from anaphylaxis.

The undersigned members of the Food Allergy Collaborative and additional organizations thank you for the opportunity to offer these comments in support of and with hope that the FDA Pulmonary-Allergy Drugs Advisory Committee will favorably recommend the approval of needle-free epinephrine nasal spray for the emergency treatment of allergic reactions (Type I) including anaphylaxis in adults and children  $\geq 30$  kilograms. If approved, we recommended that patients and caregivers undergo shared decision-making with their healthcare providers to determine which option is best for them.

**Supporting members of the Food Allergy Collaborative:**



[FARE \(Food Allergy Research & Education\)](#)



[Allergy & Asthma Network](#)



[AllergyStrong](#)



[Asthma and Allergy Foundation of America](#)



[Elijah-Alavi Foundation Inc.](#)



[Food Allergy & Anaphylaxis Connection Team \(FAACT\)](#)



[Food Equality Initiative](#)

**Additional organizations supporting epinephrine nasal spray:**



[Campaign Urging Research for Eosinophilic Disease](#)



[The Food Allergy Counselor](#)



[National Association of School Nurses](#)



[The Pennsylvania Avenue Baptist Church](#)

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