



AAFA's Statement Regarding the FDA Decision on Needle-Free Epinephrine Nasal Spray

Washington, D.C., September 20, 2023 – The Asthma and Allergy Foundation of America (AAFA) is disappointed that the epinephrine nasal spray known as neffy® did not receive FDA approval but understands the agency is requesting additional data.

Currently, epinephrine is only available in devices that use needles. A nasal spray would give people managing severe allergic reactions (anaphylaxis) more options. And as [AAFA told the FDA earlier this year, people at risk of anaphylaxis deserve to have a choice in treatment](#). In an AAFA study on food allergies in 2019, nearly three out of four people reported not using or receiving a dose of epinephrine during a recent severe allergic reaction. Fear of epinephrine and needle phobia are significant reasons why people are hesitant or delay treatment for a condition that requires immediate action.

Drug safety and efficacy are important to patients and caregivers. Epinephrine itself has a long-proven safety record. The FDA has requested an additional study on epinephrine nasal spray use by people with allergic rhinitis – which could further delay this product from getting approval by at least a year.

We hope needle-free epinephrine drug manufacturers and the FDA are able to find solutions to bring needle-free options to the market sooner rather than later. However, AAFA encourages support for the scientific process for drug development and urges participation in future clinical trials.

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About AAFA

Founded in 1953, AAFA is the oldest and largest non-profit patient organization dedicated to saving lives and reducing the burden of disease for people with asthma, allergies and related conditions through research, education, advocacy and support. AAFA offers extensive support for individuals and families affected by asthma and allergic diseases, such as food allergies and atopic dermatitis (eczema). Through its online patient support communities, network of local chapters and affiliated support groups, AAFA empowers patients and their families by providing practical, evidence-based information and community programs and services. AAFA is the only asthma and allergy patient advocacy group that is certified to meet the standards of excellence set by the National Health Council. For more information, visit: aafa.org and kidswithfoodallergies.org