ARS Pharmaceuticals Receives FDA Approval to Remove Age Requirement From neffy® 1 mg (epinephrine nasal spray) Label

March 27, 2026

*Children were previously required to weigh ≥33 lbs. and <66 lbs. and be at least four years of age to receive **neffy** 1 mg dose - approval enables families of younger children within the weight range to access a needle-free epinephrine without age restrictions*

*Updated labeling recommends storage in blister packaging or a **neffy** carrying case; ARS Pharma currently makes carrying cases available and will include one with each prescription beginning this summer*

SAN DIEGO, March 27, 2026 (GLOBE NEWSWIRE) -- ARS Pharmaceuticals, Inc. (Nasdaq: SPRY), a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis, announced today that the U.S. Food and Drug Administration (FDA) has approved updating the ***neffy***® 1 mg (epinephrine nasal spray) prescribing information to remove the age criteria so all children and adults who weigh 33 lbs. or more can utilize ***neffy*** for the emergency treatment of Type 1 allergic reactions, including anaphylaxis. Prior to the update, pediatric patients needed to meet a weight requirement and be at least four years of age. Additionally, the label update recommends patients carry ***neffy*** in the blister packaging or in the ***neffy*** carrying case. The company currently offers patients a case designed specifically to hold two ***neffy*** devices, free of charge, at www.neffy.com and will begin including the carrying case in each prescription carton this summer.

"We are very pleased that based on clinical data presented to FDA for ***neffy***, that the Agency removed the age requirement in the indication. This is a major advancement for the families with small children who live with the constant worry of severe allergic reactions in their youngest children," said Richard Lowenthal, Co-Founder, President, and CEO of ARS Pharma. "Approximately one-quarter of patients requiring epinephrine are children weighing ≥33 lbs. and <66 lbs., including approximately 25% under the age of four. Caregivers often face tremendous fear administering needle-based treatment options but[1] now, ***neffy*** can be used safely in our most vulnerable young patients (≥33 lbs. and <66 lbs.), without age restrictions. This gives families access to a needle-free option that is simple to use, easy to carry and designed to help them act quickly with confidence during emergencies."

"Severe allergic reactions are a major concern in early childhood and parents often delay treatment because they are afraid of hurting their child with a needle-injector or accidentally injecting themselves," said Dr. Nicole Chase, MD, Allergy/Immunology and Pediatrics. "Having a needle-free epinephrine treatment available for anyone who meets the weight criteria is an important step forward, in broadening access, lowering treatment hurdles, and supporting caregivers who are doing everything they can to protect their children."

Other label updates from the FDA included more flexible guidance around sniffing, temperature excursions and freezing. Specifically, language was updated to explain that even if a patient sniffs in after dosing with ***neffy*** that management of the event is the same as without sniffing, and if symptoms improve within 5 minutes, additional dosing of ***neffy*** is not necessary. ***neffy*** may be used once thawed if accidentally frozen, and high temperature excursions (up to 122^{o}F) are allowed.

neffy is available in two doses. ***neffy*** 1 mg is for patients who weigh ≥33 lbs. and <66 lbs. (15 kg to <30 kg) and ***neffy*** 2 mg is the recommended dosage for children and adults who weigh 66 lbs. (≥30 kg) or more.

About *neffy*®

neffy is a nasal spray used for emergency treatment of allergic reactions including anaphylaxis, in adults and children who weigh 33 lbs. or greater.

INDICATION AND IMPORTANT SAFETY INFORMATION FOR ***neffy*** (epinephrine nasal spray)

INDICATION

neffy is indicated for emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 33 lbs. or greater.

IMPORTANT SAFETY INFORMATION

neffy contains epinephrine, a medicine used to treat allergic emergencies (anaphylaxis). Anaphylaxis can be life-threatening, can happen in minutes, and can be caused by stinging and biting insects, allergy injections, foods, medicines, exercise, or other unknown causes.
Always carry two ***neffy*** nasal sprays with you because you may not know when anaphylaxis may happen and because you may need a second dose of ***neffy*** if symptoms continue or come back. Each ***neffy*** contains a single dose of epinephrine. ***neffy*** is for use in the nose only.

Use ***neffy*** right away, as soon as you notice symptoms of an allergic reaction. If symptoms continue or get worse after the first dose of ***neffy***, a second dose is needed. If needed, administer a second dose using a new ***neffy*** in the same nostril starting 5 minutes after the first dose. Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using ***neffy***.

Tell your healthcare provider if you have underlying structural or anatomical nasal conditions, about all the medicines you take, and about all your medical conditions, especially if you have heart problems, kidney problems, low potassium in your blood, Parkinson's disease, thyroid problems, high blood pressure, diabetes, are pregnant or plan to become pregnant, or plan to breastfeed.

Tell your healthcare provider if you take or use other nasal sprays or water pills (diuretics) or if you take medicines to treat depression, abnormal heart beats, Parkinson's disease, heart disease, thyroid disease, medicines used in labor, and medicines to treat allergies. ***neffy*** and other medications may affect each other, causing side effects. ***neffy*** may affect the way other medicines work, and other medicines may affect how ***neffy*** works.

***neffy* may cause serious side effects. If you have certain medical conditions or take certain medicines, your condition may get worse, or you may have more or longer lasting side effects when you use *neffy*.**

Common side effects of ***neffy*** include: nasal discomfort, headache, throat irritation, chest and nasal congestion, feeling overly excited, nervous or anxious, nose bleed, nose pain, sneezing, runny nose, dry nose or throat, tingling sensation, including in the nose, feeling tired, dizziness, nausea, and vomiting.

Tell your healthcare provider if you have any side effects that bother you or that do not go away after using ***neffy***.

These are not all of the possible side effects of ***neffy***. Call your healthcare provider for medical advice about side effects. To report side effects, contact ARS Pharmaceuticals Operations, Inc. at **1-877-MY-NEFFY (877-696-3339)** or the FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please see the full Prescribing Information and Patient Information for *neffy*.

About Type I Allergic Reactions Including Anaphylaxis
Type I allergic reactions are serious and potentially life-threatening events that can occur within minutes of exposure to an allergen and require immediate treatment with epinephrine, the only FDA-approved medication for these reactions. While epinephrine auto-injectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation. These limitations include fear of the needle, lack of portability, needle-related safety concerns, lack of reliability, and complexity of the devices. There are approximately 40 million people in the United States who experience Type I allergic reactions. Of this group, over the last three years, approximately 20 million people have been diagnosed and treated for severe Type I allergic reactions that may lead to anaphylaxis, but (in 2023, for example) only 3.2 million filled their active epinephrine auto-injector prescription, and of those, only half consistently carry their prescribed auto-injector. Even if patients or caregivers carry an auto-injector, more than half either delay or do not administer the device when needed in an emergency.

About ARS Pharmaceuticals, Inc.
ARS Pharma is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The Company is commercializing ***neffy***® (trade name **EUR*neffy***® in the EU and 优敏速® in China), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult patients and pediatric patients who weigh 33 lbs. or greater, and in the EU for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. For more information, visit www.ars-pharma.com.

Forward-Looking Statements
Statements in this press release that are not purely historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to: the patient benefits and effectiveness of ***neffy***, including its needle-free, compact, portable and easy to use design, temperature stability and temperature-handling flexibility, and extended shelf life; evaluations, expectations and judgments regarding the impact of the updated ***neffy*** 1 mg prescribing information on families and caregivers; ARS Pharma’s plan to including a ***neffy*** carrying case with each prescription carton this summer; and other statements that are not historical fact. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as “anticipate,” “believe,” “can,” “could,” “expect,” “if,” “may,” “on track to/for,” “potential,” “plan,” “will,” “would,” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon ARS Pharmaceuticals’ current expectations and involve assumptions that may never materialize or may prove to be incorrect.

Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation: potential safety and other complications from ***neffy***; the ability to obtain and maintain regulatory approval for ***neffy*** in its currently approved indications; the scope, progress and expansion of developing and commercializing ***neffy***; the scope, progress and expansion of developing our intranasal epinephrine technology; clinical trial results; the potential for governments and payors to delay, limit or deny coverage for ***neffy***; the size and growth of the market for ***neffy*** and the rate and degree of market acceptance thereof vis-à-vis intramuscular injectable products; ARS Pharma’s ability to protect its intellectual property position; and the impact of government laws, regulations and policies. Additional risks and uncertainties that could cause actual outcomes and results to differ materially from those contemplated by the forward-looking statements are included under the caption “Risk Factors” in ARS Pharma’s Annual Report on Form 10-K for the year ended December 30, 2025, filed with the SEC on March 9, 2026. This document can also be accessed on ARS Pharma’s website at www.ars-pharma.com by clicking on the link “Financials & Filings” under the “Investors & Media” tab.

The forward-looking statements included in this press release are made only as of the date hereof. ARS Pharma assumes no obligation and does not intend to update these forward-looking statements, except as required by law. For more information, visit www.ars-pharma.com, and follow us on LinkedIn and X.

ARS Investor Contact:
Justin Chakma
ARS Pharmaceuticals
justinc@ars-pharma.com

ARS Media Contact:
Christy Curran
Sam Brown Inc.
615.414.8668
christycurran@sambrown.com

Reference:

1. IQVIA MIDAS Database