DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Richard E. Lowenthal, MSc, MSEL
ARS Pharmaceutical Operations, Inc.
11682 El Camino Real
Suite 120
San Diego, CA 92130

RE: NDA 214697
NEFFY® (epinephrine nasal spray)
MA 250

Dear Richard Lowenthal:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (NEF-US-0882-1) (TV ad) for NEFFY® (epinephrine nasal spray) (Neffy) submitted by ARS Pharmaceutical Operations, Inc. (ARS) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Neffy and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Prior Communications

OPDP notes that the Untitled Letter dated September 9, 2025, to ARS addressed similar claims and representations for Neffy in the TV ad addressed in this letter. In the correspondence, FDA requested that ARS take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that were misleading as described). OPDP is concerned that ARS appears to be promoting Neffy using similar claims and representations in a misleading manner.

The TV ad includes the following claims (in pertinent part):

- “No needles! Goodbye!” (Jingle, 0:04 and 0:53)
- “Goodbye, needle fear.” (Audio voiceover (VO), 0:26)

These claims are misleading because they suggest that patients will be able to completely avoid using any injectable treatments for emergency treatment of allergic reactions (i.e., say “goodbye” to needles) when this has not been demonstrated. According to the FDA-approved Patient Information (PPI) for Neffy, “**When you have an allergic emergency (anaphylaxis)… Get emergency medical help for further treatment of the allergic emergency (anaphylaxis), if needed after using neffy**” (emphasis original), which may require patients to receive an injectable product, such as epinephrine and/or other injectable treatments. These claims also misleadingly suggest that Neffy will eliminate patients’

concerns in terms of needle fear when this has not been demonstrated. FDA is unaware of any evidence to support suggestions that treatment with Neffy has an effect on needle fear or otherwise has a positive impact on a patient's mental or emotional state regarding needles.

We acknowledge that the TV ad includes the SUPER, "If additional emergency medical help is needed to treat your allergic reaction, treatments may include other injectable products." However, inclusion of this statement in this promotional communication does not mitigate the misleading suggestions regarding Neffy described above.

The TV ad also includes the following claims (in pertinent part):

- "Hello, getaways. Goodbye, stressful days." (VO, 0:19)
- "Hello, celebration. Goodbye, hesitation." (VO, 0:22)

These claims are misleading because they suggest that Neffy alone can provide assurance that a patient with a history of life-threatening allergic reactions does not need to worry or take precautionary measures to avoid exposure to allergens. Specifically, the use of "goodbye" in these claims misleadingly suggests that a person who needs Neffy for the emergency treatment of allergic reactions can feel completely free from stressful days (for example, when they travel), or hesitation around attending events, provided they have access to Neffy, when this is not the case. Patients with severe allergies still must consider their particular situation in order to take appropriate precautionary measures to avoid allergen exposure and a potentially life-threatening anaphylactic reaction, regardless of access to Neffy treatment.

In addition, the TV ad is misleading regarding the storage and handling of Neffy. The TV ad includes multiple presentations (i.e., 0:03, 0:06, 0:14 and 0:17), of the Neffy device out of its blister packaging and being placed in a carry case in various bags and a pocket. According to the "**How should I store neffy?**" section of the PPI for Neffy, patients should, "Store neffy nasal spray in the blister pack until ready to use." Similarly, the PATIENT COUNSELING INFORMATION section of the FDA-approved product labeling (PI) for Neffy directs healthcare providers to, "Advise patients and/or caregivers to store neffy nasal spray in the blister pack until ready to use." These presentations are concerning from a public health perspective because each Neffy device can only be sprayed one time, so that accidental activation and/or device disassembly due to improper storage and handling may result in patients not being able to administer Neffy in an emergency.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Neffy and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that ARS take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Neffy that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Neffy.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 250 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 0369 under NDA 214697. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Jennifer Chen, PharmD, MBA
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Susannah O'Donnell, MPH, RAC
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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

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