

Division of Pulmonology, Allergy, and Critical Care Memorandum

Date	February 23, 2026
NDA	214697
Drug Name(s)	neffy (epinephrine nasal spray)
Sponsor	ARS Pharmaceuticals
Indication	emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients 4 years of age and older who weigh 15 kg or greater
Clinical Review Team	Jennifer Lan, MD Miya Paterniti, MD

This addendum supplements the Division of Pulmonology, Allergy, and Critical Care (DPACC) clinical memorandum for NDA 214697 (neffy/epinephrine nasal spray) efficacy supplement S-002, dated February 19, 2026, in DARRTs. This addendum addresses financial disclosure.

The proposed indication change for epinephrine nasal spray was supported by evidence from a Valtoco pediatric pharmacokinetic trial (DIAZ.001.008) conducted for the Valtoco efficacy supplement (NDA 211635, S-010) which extended the indication from 6 years of age to patients aged 2 to 5 years for the treatment of seizure clusters. Financial disclosures for Trial DIAZ.001.008 are included in the clinical review for NDA 211635, S-010, dated December 17, 2024.

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/s/

JENNIFER P LAN
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MIYA O PATERNITI
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