



NDA 208969/S-002

**SUPPLEMENT APPROVAL**

Amphastar Pharmaceuticals, Inc.  
Attention: Magda Albedrop  
Associate Director, Regulatory Affairs  
11570 6th Street  
Rancho Cucamonga, CA 91730

Dear Magda Albedrop:

Please refer to your supplemental new drug application (sNDA) dated August 21, 2025, and received August 22, 2025, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Rextovy (naloxone hydrochloride) nasal spray, 4 mg per 0.25 mL.

This “Prior Approval” supplemental new drug application provides for the full prescription to nonprescription switch of Rextovy (naloxone hydrochloride) nasal spray, 4 mg.

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**LABELING**

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the enclosed labeling, and labeling and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Draft Labeling</b>	<b>Date submitted</b>
Device (Nasal Spray) Label (4 mg naloxone HCl)	February 25, 2026
Blister “Peel Lid” Label (4 mg naloxone HCl)	February 25, 2026
User Guide “Directions”	March 12, 2026
2-ct Outer Carton (4 mg naloxone HCl)	March 12, 2026

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 208969/S-002.**” Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future (e.g., package sizes containing fewer than two doses), a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of use must be submitted. We encourage you to contact us about the content and format of such a supplement prior to submission.

## **DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.<sup>2</sup> Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

## **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(C) to FDA on Form FDA 3542 within 30 days after the date of approval of this supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). Until you submit Form FDA 3542 (as required by 21 CFR 314.53(d)(2)(i)(C)) or until 30 days after the date of approval of this supplement (whichever comes first), FDA will carry over (i.e., continue to list) the patent information listed for this product in the prescription section of the Orange Book as of the date of approval of this supplement requesting to change the drug product from prescription use to over-the-counter use. If you do not submit Form FDA 3542 by the end of the 30-day period, the carried-over patent information will be removed from the

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<sup>1</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Orange Book at the end of the 30-day period, unless information must remain listed in order to preserve a first applicant's eligibility for 180-day exclusivity, in which case the patent information would be identified with a patent delist request flag until the patent is removed from the Orange Book.

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Cynthia Kim, PharmD, BCPS, Senior Regulatory Project Manager, at [Cynthia.Kim@fda.hhs.gov](mailto:Cynthia.Kim@fda.hhs.gov) or (301) 796-0879.

Sincerely,

*{See appended electronic signature page}*

Nushin Todd, MD, PhD  
Director  
Division of Nonprescription Drugs I  
Office of Nonprescription Drugs  
Office of New Drugs  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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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.**  
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/s/  
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NUSHIN F TODD  
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