

NDA 208411/S-009

**SUPPLEMENT APPROVAL**

Emergent Product Development  
Gaithersburg, Inc.  
Attention: Thomas Bolton  
Director, Regulatory Affairs  
300 Professional Drive  
Gaithersburg, MD 20879

Dear Thomas Bolton:

Please refer to your supplemental new drug application (sNDA) dated and received May 23, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Narcan (naloxone hydrochloride) nasal spray, 4 mg.

This “Prior Approval” supplemental new drug application provides for updates to the Quick Start Guide insert to incorporate the complete Drug Facts Label (DFL).

**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 FPL must be identical to the enclosed labeling described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Draft Labeling</b>	<b>Date</b>
Narcan 2-sided Quick Start Guide	May 23, 2025

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 208411/S-009.**” 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)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53 (d)(2)(ii)(B) and 314.53(f)(2)(iv).

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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>

## **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 Tam Dinh, PharmD, Regulatory Project Manager, at 240-402-6284 or Tam.Dinh@fda.hhs.gov.

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):

- Quick Start Guide 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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