NDA 208411/S-006

SUPPLEMENT APPROVAL

Emergent Operations Ireland Limited
c/o Emergent BioSolutions Inc
Attention: Shelly Shirkey
Sr. Manager Regulatory Affairs
300 Professional Drive
Gaithersburg, MD 20879

Dear Ms. Shirkey:

Please refer to your supplemental new drug application (sNDA) dated and received on September 29, 2022, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Narcan (naloxone hydrochloride) nasal spray, 4 mg.

This supplemental new drug application provides for the full prescription to nonprescription switch for Narcan (naloxone hydrochloride) nasal spray.

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.

Submitted Draft Labeling	Date Submitted
2-Count Outer Carton for Retail Distribution (i.e., Retail)	March 28, 2023
2-Count Outer Carton Not for Retail Distribution (i.e., Non-Retail)	March 28, 2023
Immediate Container (Blister Package) Label	March 24, 2023
Quick Start Guide (QSG)	March 24, 2023
Drug-Delivery Device Label	March 08, 2023

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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 208411/S-006**." 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.[2] 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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[1] 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.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 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).

Your product is a Part 3 combination product (21 CFR 3.2(e)); therefore, you must also comply with postmarketing safety reporting requirements for an approved combination product (21 CFR 4, Subpart B). Additional information on combination product postmarketing safety reporting is available at FDA.gov.[3]

[3] https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products

If you have any questions, call Phong Pham, PharmD, MBA, Regulatory Project Manager, at (301) 837-7656 or email at Phong.Pham@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Teresa Buracchio, MD
Director (Acting)
Office of Neuroscience
Office of New Drugs
Center for Drug Evaluation and Research

and

{See appended electronic signature page}

Theresa Michele, MD
Director
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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/

TERESA J BURACCHIO
03/28/2023 10:00:04 PM

THERESA M MICHELE
03/29/2023 07:41:36 AM