4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-0148]

Emergent Biosolutions Inc.; Withdrawal of Approval of a Supplemental New Drug Application for NARCAN (Naloxone Hydrochloride) Nasal Spray, 2 Milligrams/0.1 Milliliter

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing the approval of a supplemental new drug application (sNDA) for NARCAN (naloxone hydrochloride) nasal spray, 2 milligrams (mg)/0.1 milliliter (mL), held by Emergent Biosolutions Inc., 400 Professional Dr., Suite 400, Gaithersburg, MD 20879. Emergent Biosolutions, Inc., has notified the Agency in writing that NARCAN (naloxone hydrochloride) nasal spray, 2 mg/0.1 mL, is not marketed and has requested that approval of the sNDA be withdrawn. This action has no impact on the continued approval and marketing of NARCAN (naloxone hydrochloride) nasal spray, 4 mg/0.1 mL.

DATES: Applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Ayako Sato, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD 20993-0002, 240-402-4191.

SUPPLEMENTARY INFORMATION: Emergent Biosolutions, Inc., has informed FDA that NARCAN (naloxone hydrochloride) nasal spray, 2 mg/0.1 mL, is not marketed and has requested that FDA withdraw approval of sNDA-001 208411, approved on January 24, 2017, under the process in § 314.150(c) (21 CFR 314.150(c)). Emergent Biosolutions, Inc., has also, by its request, waived its opportunity for a hearing. Withdrawal of approval of an application under § 314.150(c) is without prejudice to refiling.

Therefore, approval of the sNDA for NARCAN (naloxone hydrochloride) nasal spray, 2 mg/0.1 mL, is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Introduction or delivery for introduction into interstate commerce of such product without an approved new drug application violates section 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Any NARCAN (naloxone hydrochloride) nasal spray, 2 mg/0.1 mL that is in inventory on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventory has been depleted or the drug product has reached its expiration date or otherwise becomes violative, whichever occurs first.

Dated: February 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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