guidance for industry entitled ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities,'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/repackaging-certain-human-drug-products-pharmacies-and-outsourcing-facilities*), when a State-licensed pharmacy, Federal facility, or outsourcing facility repackaged an FDA-approved propofol injectable emulsion, 10 mg/mL product, or combined different FDA-approved propofol injectable emulsion, 10 mg/mL products in the same container.

As stated above, propofol had been on FDA's drug shortage list when FDA issued the guidance document. Based on our review of currently available data, we have determined that the shortage of propofol drug products has been resolved, with manufacturers reporting having an adequate supply of the drug products. Further, hospitals have not been reporting to FDA that they are having difficulty obtaining adequate supplies of propofol drug products. Accordingly, we have determined that the circumstances related to this temporary policy have evolved such that the temporary policy is no longer needed, and the guidance document should be withdrawn.

II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is March 13, 2023. The COVID–19 pandemic is a constantly evolving situation. FDA continues to assess these circumstances and should the current data change to indicate that the demand of propofol drug product has again outstripped supply before March 13, 2023, FDA may revise this date.

Dated: February 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02809 Filed 2–9–23; 8:45 am]

BILLING CODE 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 February 10, 2023.

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 February 10, 2023. 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 February 10, 2023 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB). The meeting will be held in-person at the Hubert H. Humphrey building in Washington, DC, and will be open to the public; the meeting will be streamed live on *hhs.gov/live.* A pre-registered public comment session will be held during the meeting. Pre-registration is required for members of the public who wish to present their comments in-person at the meeting. Individuals who wish to send in their written public comment should send an email to *CARB@hhs.gov.* Registration information is available on the website *http://www.hhs.gov/paccarb* and must be completed by March 17, 2023 for the March 23–24, 2023 Public Meeting. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/paccarb* on the Upcoming Meetings page.

DATES: The meeting is scheduled to be held on March 23–24, 2023, from 10 a.m. to 4 p.m. ET (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the website for the PACCARB at *http://www.hhs.gov/paccarb* when this information becomes available. Pre-registration for attending the meeting is strongly suggested and should be completed no later than March 17, 2023.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201. All in-person attendees must have a valid U.S. government issued I.D. to enter the building. All non-U.S. citizen in-person attendees must contact *CARB@hhs.gov* at least two weeks prior to the meeting to accommodate the HHS security vetting process. The meeting can also be accessed through a live webcast on the day of the meeting. Additional instructions regarding attending this meeting virtually will be