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temporary policy have evolved such that the temporary policy is no longer needed, and the guidance document should be withdrawn.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.

[FR Doc. 2023–02823 Filed 2–9–23; 8:45 am]

BILLING CODE 4164–01–P

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

posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

FOR FURTHER INFORMATION CONTACT: Jomana Musmar, M.S., Ph.D., Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Rockville, MD 20852. Phone: 202–746–1512; Email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB), established by Executive Order 13676, is continued by section 505 of Public Law 116–22, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (PAHPAIA). Activities and duties of the PACCARB are governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of federal advisory committees.

The PACCARB shall advise and provide information and recommendations to the Secretary of Health and Human Services (Secretary) regarding programs and policies intended to reduce or combat antibiotic-resistant bacteria that may present a public health threat and improve capabilities to prevent, diagnose, mitigate, or treat such resistance. The PACCARB shall function solely for advisory purposes.

Such advice, information, and recommendations may be related to improving: the effectiveness of antibiotics; research and advanced research on, and the development of, improved and innovative methods for combating or reducing antibiotic resistance, including new treatments, rapid point-of-care diagnostics, alternatives to antibiotics, including alternatives to animal antibiotics, and antimicrobial stewardship activities; surveillance of antibiotic-resistant bacterial infections, including publicly available and up-to-date information on resistance to antibiotics; education for health care providers and the public with respect to up-to-date information on antibiotic resistance and ways to reduce or combat such resistance to antibiotics related to humans and animals; methods to prevent or reduce the transmission of antibiotic-resistant bacterial infections; including stewardship programs; and coordination with respect to international efforts in order to inform and advance the United States capabilities to combat antibiotic resistance.

The March 23–24, 2023 will be a two-day meeting that will focus on the report out from the Pandemic Preparedness Working Group as they present their findings in response to the 2022 task from the HHS Secretary in a report with recommendations to the full PACCARB for deliberation and vote. Upon completion of the voting process, the PACCARB will honor its retiring members. The meeting will also include updates from the international sector on progress in the ongoing fight against antimicrobial resistance and an exploration of future topics for the PACCARB to consider in the following year. The meeting agenda will be posted on the PACCARB website at *http://www.hhs.gov/paccarb* when it has been finalized. All agenda items are tentative and subject to change. Instructions regarding attending the meeting virtually will be posted at least one week prior to the meeting at: *http://www.hhs.gov/paccarb.*

Members of the public will have the opportunity to provide comments in-person during the March meeting by pre-registering online at *http://www.hhs.gov/paccarb.* Pre-registration is required for participation in this session with limited spots available. Written public comments can also be emailed to *CARB@hhs.gov* by midnight March 17, 2023 and should be limited to no more than one page. All public comments received prior to March 17, 2023, will be provided to the PACCARB members. Additionally, companies and/or organizations involved in combating antibiotic resistance have an opportunity to present their work to members of the PACCARB live during an Innovation Spotlight. Pre-registration is required for participation, with limited spots available. All information regarding this session can also be found online at *http://www.hhs.gov/paccarb.*

Dated: January 12, 2023.

Jomana F. Musmar,

Designated Federal Officer, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health.

[FR Doc. 2023–02921 Filed 2–9–23; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Termination of Declaration Authorizing Emergency Use of New In Vitro Diagnostics for Detection of Enterovirus D68

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

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 6, 2015, pursuant to section 564 of the FD&C Act, Sylvia M. Burwell, former Secretary of HHS, determined that there was a significant potential for a public health emergency that had a significant potential to affect national security or the health and security of United States citizens living abroad and that involved enterovirus D68 (EV–D68). Also on February 6, 2015, based on that determination, former Secretary Burwell declared that circumstances existed justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section. As of September 2022, the Centers for Disease Control and Prevention's (CDC's) EV–D68 2014 rRT–PCR for which an EUA was issued is no longer produced and all test kits were destroyed. CDC's EV–D68 2014 rRT–PCR was never distributed. On February 6, 2023, pursuant to section 564 of the FD&C Act, the Secretary of HHS determined that there is no longer a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves EV–D68. The Secretary of HHS also determined that circumstances justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 no longer exist. Based on these determinations, the Secretary of HHS terminated the declaration, effective February 20, 2023, that circumstances justifying the authorization of emergency use of new in vitro diagnostics for detection of EV–D68 exist.

DATES: Termination of the declaration is effective February 20, 2023.

FOR FURTHER INFORMATION CONTACT: Dawn O'Connell, Assistant Secretary for Preparedness and Response,