composition of the test and reference diets in a PER study should be comparable. We invite comments on how such comparability should be defined and how it might be achieved.

Question 10. In Appendix 6 of the draft guidance, FDA has suggested a process by which vitamin compositions of the test and reference diets can be matched to within ±20 percent. We invite comments on whether this approach is reasonable and ask you to explain your thinking. If you do not believe the approach is reasonable, please explain your reasoning and suggest an alternative approach.

Question 11. We invite comments on whether the matching of the vitamin compositions between the test and reference diets should be eliminated because, for example, vitamins such as vitamin K and vitamin B12, among others, do not impact the growth of rats during the 28-day PER study. If your answer is ''yes, the matching of vitamin compositions between test and reference diets should be eliminated,'' what do you propose as the vitamin composition for the reference diet? Please explain your reasoning. If your answer is ''no,'' please explain your reasoning.

E. Question for Section IV.B.1.g. Fiber

Question 12. We invite comment on whether fiber should be added to the PER study test and matched casein reference diets under all conditions, under specified conditions, or not added at all. If your answer is ''yes, under all conditions,'' what is your proposed level of addition (*e.g.,* to match the concentrations of non-digestible fiber in the infant formula at its rate of addition)? If your answer is ''yes, under specified conditions,'' what are the specific conditions under which fiber should be added and at what concentration? If your answer is ''no, fiber should not be added,'' please explain your reasoning.

F. Question for Section IV.B.1.h. Sulfur Amino Acids (Methionine, Cystine)

Question 13. In the draft guidance, we recommend that the concentration of inorganic sulfur (*e.g.,* as sulfate salts) in the PER study casein reference control diet be adjusted to 0.964 g/kilograms diet, the content calculated from the mineral composition set forth in the AOAC Method as originally described. We also provide a procedure for matching the (methionine + cystine) concentrations in the casein reference control and test diets, and for use of this sulfur amino acid-matched group as a second casein reference control group in PER studies. This approach will reduce the risk of a failure of the PER study control group. If you think the approach is needed, please explain your reasoning. If you think that such an approach is not necessary, please explain why not. If you think that other approaches might be more helpful in reducing the risk of a failure of the reference control group, please describe such approaches and explain their advantages.

Dated: February 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02836 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–2020–D–1136]

Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID–19 Public Health Emergency; Withdrawal of Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance for industry entitled ''Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID–19 Public Health Emergency,'' which was issued in April 2020 to communicate a temporary policy regarding the repackaging or combining of propofol drug products. FDA is withdrawing this guidance document because the conditions that created the need for this policy described in the document have evolved and the policy is no longer needed.

DATES: The withdrawal date is March 13, 2023.

FOR FURTHER INFORMATION CONTACT: Kimberly Thomas, Office of Regulatory Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–2357.

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, in April 2020, the Agency published the guidance for industry entitled ''Temporary Policy on Repackaging or Combining Propofol Drug Products During the COVID–19 Public Health Emergency.'' This guidance communicated the Agency's temporary policy regarding the repackaging or combining of propofol drug products by licensed pharmacists in State licensed pharmacies, Federal facilities, and outsourcing facilities registered pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353b).[2] FDA had received reports from some hospitals that they were having difficulty obtaining adequate supplies of FDA-approved propofol injectable emulsion (propofol) products, 10 milligrams (mg) per milliliter (mL), in the presentations used to support COVID–19 patients who had been sedated and intubated, or for other procedures involved in the care of such patients. At the time the guidance was published, propofol was on FDA's drug shortage list, with several presentations on backorder or on allocation. FDA recognized that pharmacies and outsourcing facilities that had access to certain presentations of propofol drug products wanted to repackage or combine units of a finished, FDA-approved drug product to provide hospitals with presentations needed for patients with COVID–19. The guidance stated that as a temporary measure during the public health emergency related to COVID–19, or for such shorter time as FDA may announce by updating or withdrawing the guidance based on evolving needs and circumstances, FDA intended to extend, under certain circumstances described in the guidance, its existing enforcement discretion policy described in the

[1] The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19).

[2] As explained in the guidance, provided that circumstances described in the guidance were present, FDA did not intend to take action for violations of section 505 (concerning new drug applications), section 502(f)(1) (concerning labeling with adequate directions for use), and section 582 (concerning drug supply chain security) of the FD&C Act (21 U.S.C. 355, 352(f)(1), and 360eee-1) if a State-licensed pharmacy, a Federal facility, or an outsourcing facility prepared drug products as described in this guidance and met other applicable requirements. Applicable requirements included, for example, the requirement that manufacturers not adulterate a drug product by preparing, packing, or holding the drug product under insanitary conditions. See section 501(a)(2)(A) of the FD&C Act (21 U.S.C. 351(a)(2)(A)). In addition, FDA did not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act if the drug product was repackaged by a State-licensed pharmacy or a Federal facility in accordance with the conditions described in the guidance, and any applicable requirements. Finally, with respect to entities that did not qualify for the exemptions from registration under section 510 of the FD&C Act (21 U.S.C. 360), FDA did not intend to take action for violations of section 502(o) of the FD&C Act.

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]

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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