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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

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

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 guidance for industry entitled "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities," (https://www.fda.gov/regulatory-information/search-fda-guidance-

[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.

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], FDA may revise this date.

Dated: February 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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