



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-N-2057]

#### Revocation of Emergency Use of a Drug During the COVID-19 Pandemic; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorization (EUA) issued to B. Braun Melsungen AG (B. Braun Melsungen) for Propofol-Lipuro 1% injectable emulsion (Propofol-Lipuro 1% emulsion). The EUA was issued on March 12, 2021. B. Braun Melsungen informed FDA that the inventory of the Propofol-Lipuro 1% emulsion within the United States has been depleted and that B. Braun Melsungen does not intend to offer this product in the United States anymore. Because B. Braun Melsungen has notified FDA that it does not intend to offer the Propofol-Lipuro 1% emulsion in the United States anymore and requested FDA revoke the EUA for the Propofol-Lipuro 1% emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. The revocation, which includes an explanation of the reasons for the revocation, is reprinted in this document.

**DATES:** The Authorization is revoked as of April 12, 2023.

**ADDRESSES:** Submit written requests for a single copy of the EUA to the Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

**FOR FURTHER INFORMATION CONTACT:** Johanna McLatchy, Office of Executive Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, 6th Floor, Silver Spring, MD 20993-0002, 301-796-3200 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:**

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives. On March 12, 2021, FDA issued an Authorization (EUA 096) to B. Braun Melsungen for Propofol-Lipuro 1% emulsion, subject to the terms of the Authorization. Notice of the issuance of the Authorization was published in the *Federal Register* on June 23, 2021 (86 FR 32938), as required by section 564(h)(1) of the FD&C Act.

II. The Revocation

Because B. Braun Melsungen has notified FDA that it does not intend to offer the Propofol-Lipuro 1% emulsion in the United States anymore and requested FDA revoke the EUA for the Propofol-Lipuro 1% emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. The revocation in its entirety follows and provides an explanation of the reasons for revocation, as required by section 564(h)(1) of the FD&C Act.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations and revocation are available on the internet at <https://www.fda.gov/drugs/emergency-preparedness-drugs/emergency-use-authorizations-drugs-and-non-vaccine-biological-products>.



April 12, 2023

B. Braun Melsungen AG  
Attention: Kamaal Anas  
Registered Agent  
901 Marcon Boulevard  
Allentown, PA 18109

**Re: Revocation of EUA 096 – Propofol-Lipuro 1%**

Dear Mr. Anas:

This letter is in response to the request from B. Braun Melsungen AG (B. Braun Melsungen), received on February 27, 2023, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Propofol-Lipuro 1% injectable emulsion (Propofol-Lipuro 1% emulsion) issued on March 12, 2021. B. Braun Melsungen has informed the FDA that the inventory of the Propofol-Lipuro 1% emulsion within the United States has been depleted and that B. Braun Melsungen does not intend to offer this product in the United States anymore. FDA understands that B. Braun Melsungen has notified healthcare facilities and providers that have received the Propofol-Lipuro 1% emulsion under the EUA to also stop using product that remains in distribution with instructions for product return.

The authorization of a drug for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because B. Braun Melsungen has notified FDA that it does not intend to offer the Propofol-Lipuro 1% emulsion in the United States anymore and requested that FDA revoke the EUA for the Propofol-Lipuro 1% emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 096 for the Propofol-Lipuro 1% emulsion, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Propofol-Lipuro 1% emulsion is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

–/S/–

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Patrizia Cavazzoni, M.D.  
Director  
Center for Drug Evaluation and Research  
U.S. Food and Drug Administration

**Dated:** June 1, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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