pregnancy and sexually transmitted infections. The programs are required to provide education on both abstinence and contraceptive use and to offer information on adulthood preparation subjects. Data will be used to determine if the PREP grantees are meeting their programs' mission and priorities. This request includes revisions to the program-level data collection forms (Instruments 3 and 4) to *no* longer require grantees to aggregate participant survey data to the program level for submission.

Respondents: SPREP, TPREP, CPREP, and PREIS grantees; their subrecipients; and program participants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Instrument 1					
Participant entry survey	351,001	1	0.13333	46,799	15,600
Instrument 2					
Participant exit survey	320,203	1	0.11667	37,358	12,453
Instrument 3: Performance Reporting System Data Entry Form					
SPREP grantees	51	6	18	5,508	1,836
TPREP grantees	8	6	18	864	288
CPREP grantees	27	6	14	2,268	756
PREIS grantees	12	6	14	1,008	336
Instrument 4: Subrecipient Data Collection and Reporting Form					
SPREP subrecipients	259	6	14	21,756	7,252
TPREP subrecipients	27	6	14	2,268	756
CPREP subrecipients	54	6	12	3,888	1,296
PREIS subrecipients	20	6	12	1,440	480

Estimated Total Annual Burden Hours: 41,053.

Authority: Sec. 50503, Pub. L. 115–123.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–12160 Filed 6–6–23; 8:45 am]

BILLING CODE 4184–37–P

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.*

BILLING CODE 4164–01–P

U.S. FOOD & DRUG ADMINISTRATION

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.

Page 2 – B. Braun Melsungen

Sincerely,

–/S/–

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.

[FR Doc. 2023–12100 Filed 6–6–23; 8:45 am]

BILLING CODE 4164–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–1955]

E6(R3) Guideline for Good Clinical Practice; International Council for Harmonisation; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''E6(R3) Guideline for Good Clinical Practice.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance outlines modernized Good Clinical Practice considerations to guide thoughtful design and responsible conduct of clinical trials in a manner that ensures participant safety and the reliability of trial results. This draft guidance encourages innovation, focuses on quality, and establishes proportionate and risk-based approaches for conducting clinical trials, while minimizing unnecessary complexities. The draft guidance is intended to provide flexible, modern, and clear Good Clinical Practice for conducting clinical trials.

DATES: Submit either electronic or written comments on the draft guidance by September 5, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–1955 for ''E6(R3) Guideline for Good Clinical Practice.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.