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,

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