U.S. FOOD & DRUG ADMINISTRATION

May 10, 2022

Nicole Chutipisalkul
Sr. Regulatory Affairs Specialist
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Re: Revocation of EUA 050 – Propoven 2% Emulsion

Dear Ms. Chutipisalkul:

This letter is in response to the request from Fresenius Kabi USA, LLC ("Fresenius Kabi"), received on April 8, 2022, that the U.S. Food and Drug Administration (FDA) revoke the EUA for the Fresenius Propoven 2% Emulsion issued on May 8, 2020. Fresenius Kabi has informed the FDA that the inventory of the Fresenius Propoven 2% emulsion within the United States has been depleted and that Fresenius Kabi does not intend to offer this product in the United States anymore. FDA understands Fresenius Kabi has notified healthcare facilities and providers that have received the Fresenius Propoven 2% Emulsion under the EUA to also stop using this product.

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 Fresenius Kabi has notified FDA that it does not intend to offer the Fresenius Propoven 2% Emulsion in the United States anymore and requested FDA revoke the EUA for the Fresenius Propoven 2% Emulsion, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

Accordingly, FDA hereby revokes EUA 050 for the Fresenius Propoven 2% Emulsion, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Fresenius Propoven 2% 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,

Jacqueline A. O'shaughnessy -S
Digitally signed by Jacqueline A. O'shaughnessy -S
Date: 2022.05.10 12:47:10 -04'00'

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration