



EUA 000096

**EMERGENCY USE AUTHORIZATION-
REVISED FACT SHEETS**

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

RE: Emergency Use Authorization 096

Dear Ms. Stolarick:

Please refer to your Emergency Use Authorization (EUA) for emergency use of Propofol-Lipuro 1% injectable emulsion for infusion to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an Intensive Care Unit (ICU) setting during the 2019 coronavirus disease (COVID-19) pandemic issued on March 12, 2021, under section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 360bbb-3).

We refer to your submissions dated September 28 and November 4, 2021, wherein you proposed revisions to the authorized Fact Sheets for Healthcare Providers, and Patients, Parents, and Caregivers.

We have completed our review and concur with the following revisions:

1. Inclusion of information regarding administration of indicated antiepileptic medication in the Fact Sheet for Healthcare Providers.
2. Inclusion of fever as a less common side effect in the Fact Sheet for Patients, Parents, and Caregivers.
3. Inclusion of additional information regarding the less common side effect of change in color of urine in the Fact Sheet for Patients, Parents, and Caregivers.
4. Inclusion of cardiac arrest as a less common side effect in the Fact Sheet for Patients, Parents, and Caregivers.

The updated Fact Sheets for Healthcare Providers, and Patients, Parents, and Caregivers are attached to this correspondence for your reference.

By submitting these amendments for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the March 12, 2021, letter authorizing the emergency use of of Propofol-Lipuro 1% injectable emulsion

for infusion to maintain sedation via continuous infusion in patients greater than 16 years old who require mechanical ventilation in an Intensive Care Unit (ICU) setting during the 2019 coronavirus disease (COVID-19) pandemic.

If you have any questions, call Allison Meyer, Senior Regulatory Health Project Manager, at (301) 796-1258.

Sincerely,

--/S/--

Rigoberto Roca, MD
Director
Division of Anesthesiology, Addiction Medicine,
and Pain Medicine
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- **EUA Fact Sheets**
 - Healthcare Provider Factsheet
 - Patient Factsheet