NDA 016812/S-052

SUPPLEMENT APPROVAL

Par Sterile Products LLC
Attention: Roxana Nadolny
Manager, Regulatory Affairs
Six Ram Ridge Road
Chestnut Ridge, NY 10977

Dear Ms. Nadolny:

Please refer to your Supplemental New Drug Application (sNDA) dated March 11, 2022, received March 11, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ketalar (ketamine hydrochloride injection).

We also refer to our approval letter dated August 23, 2022, which contained the following error: The product name within the provides for statement is incorrect.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 23, 2022, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an alternate (b) (4) area for Ketalar (b) (4) an alternate (b) (4) area for Ketalar, in addition to the approved (b) (4) at the Rochester, MI facility.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D
Branch Chief, B3
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Gurpreet
Gill Sangha

Digitally signed by Gurpreet Gill Sangha
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