



NDA 214313/S-004

SUPPLEMENT APPROVAL

Baxter Healthcare Corp
Attention: Kirsten Hesemann
Senior Manager, Regulatory Affairs
One Baxter Parkway
Deerfield, IL 60015

Dear Ms. Hesemann:

Please refer to your supplemental New Drug Application(s) (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA), your supplemental Abbreviated New Drug Application(s) (sANDA) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (FDCA), and all amendments, for the following products:

Supplemental Application	Product Information	Submit Date	FDA Received Date
NDA 214313/S-004	Norepinephrine Bitartrate Injection, Solution	December 19, 2023	December 19, 2023
ANDA 211965/S-004	Magnesium Sulphate	December 19, 2024	December 19, 2023
ANDA 211966/S-005	Magnesium Sulphate	December 19, 2023	December 19, 2023

We also refer to our approval letter dated June 11, 2024, which contained the following error: ANDA application numbers listed in the communication had a typographical error.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain June 11, 2024, the date of the original approval letter.

This “Changes Being Effected” supplemental new drug application provides for Change in the control strategy of implementation of 100% visual inspection of containers for particulate matter on filled units.

APPROVAL

We have completed our review of this supplemental application, as amended. 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, contact Grafton Adams, Senior Regulatory Business Process Manager, at grafton.adams@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Gurpreet Gill-Sangha, Ph.D.
Supervisor
Division of Product Quality Assessment II
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research



Gurpreet
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Digitally signed by Gurpreet Gill Sangha

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