



NDA 020309/S-032

APPROVAL LETTER

Hospira, Inc.
Attention: Kathleen Enger
Senior Manager, Global Regulatory Affairs
275 North Field Drive
Building H1
Lake Forest, IL 60045

Dear Ms. Enger:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 31, 2022, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Magnesium Sulfate in Water for Injection.

This Prior Approval supplemental new drug application provides for:

- [REDACTED] (b) (4) as an alternate drug product manufacturing site
- New flexible container closure system
- Manufacturing [REDACTED] (b) (4) changes
- Removal of [REDACTED] (b) (4) for the drug product
- Revisions to flexible container and overwrap labeling

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 020309/S-032.**” Approval of this submission by FDA is not required before the labeling is used.

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

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If you have any questions, contact Olubusola (Busola) Baoku, Regulatory Business Process Manager, at (301) 796 – 0191 or Olubusola.Baoku@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality (OPQ)
Center for Drug Evaluation and Research

Enclosure:

Carton and Container Labeling



Ramesh
Raghavachari

Digitally signed by Ramesh Raghavachari

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