DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-309/S-015

Hospira, Inc.
Attention: Julie Gibson
Associate Quality Regulatory Affairs
275 N. Field Drive
Lake Forest, IL 60045-5046

Dear Ms. Gibson:

Please refer to your supplemental new drug application dated July 25, 2006, received July 26, 2006, and submitted under to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Magnesium Sulfate in Water for Injection, 2 g/50 mL and 4 g/100 mL.

We acknowledge receipt of your submission dated July 31, 2006.

This "Changes Being Effected in 30 days" supplemental new drug application provides for adding a new strength, 2 g/50 mL, of the drug product and a revision of the storage condition statement to delete "Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat."

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the labeling text submitted on July 25, 2006.

Please submit the final printed carton and container labels electronically that are identical to the submitted draft carton and container labels. Alternately, you may submit 20 paper copies of the final printed carton and container labels as soon as they are available but no more than 30 days after they are printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved supplemental NDA 20-309/S-015**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Susan Jenney, Regulatory Health Project Manager, at (301) 796-0062.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Hasmukh Patel

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