DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-916/S-004

Hospira, Inc.
275 N. Field Drive
Dept. 0389, Bldg. H2
Lake Forest, IL 60045-5046

Attention: Judith Zutkis
Associate Director, Global Regulatory Affairs

Dear Ms. Zutkis:

Please refer to your supplemental new drug application dated December 5, 2005, received December 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Morphine Sulfate Injection, USP, Preservative Free, 1.0 mg/mL.

We acknowledge receipt of your submissions dated January 10, February 27, June 26, and October 10, 2006.

Your submission of June 26, 2006 constituted a complete response to our April 7, 2006, action letter.

This supplemental new drug application provides for a new strength, Morphine Sulfate Injection, USP, Preservative Free, 5 mg/mL.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert submitted June 26, 2006, immediate container and carton labels submitted October 10, 2006).

Please submit either an electronic version or 20 paper copies of the FPL as soon as it is available (no more than 30 days after it is printed). If paper copies are submitted, individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 19-916/S-004**." 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

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 Lisa Basham, Regulatory Project Manager, at (301) 796-1175.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure

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

/s/

Bob Rappaport

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