DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-025/S-040

Hospira, Inc.
Attention: Carol M. Stephany
Manager, Global Regulatory Affairs
275 N. Field Drive
D-0389, Building H2
Lake Forest, IL 60045-5046

Dear Ms. Stephany:

Please refer to your supplemental new drug application dated March 29, 2006, received March 30, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for THAM (tromethamine) Injection.

We acknowledge receipt of your submissions dated April 28 and July 10, 2006.

This supplemental new drug application provides for an alternate manufacturing facility in (b)(4). Changes proposed for the new facility include (b)(4). It also provides for revisions to the **HOW SUPPLIED** section of the package insert and to the container label. Finally, it provides for a new bottle and bottle hanger combination. This is the first of a planned bundle supplement.

We completed our review of this application 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 (text for the package insert and immediate container labels).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 13-025/S-040**." 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 (21 CFR 314.80 and 314.81).

If you have any questions, call Pat Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

James Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Assessment
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure: draft package insert
draft container label

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

/s/

Jim Vidra

7/20/2006 03:02:15 PM