DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-957/S-039

Hospira, Inc
8484 Highway 70 West
Clayton, NC 27520

Attention: Beth McLamb
Plant Quality Assurance Manager

Dear Ms. McLamb:

Please refer to your new drug application (NDA) dated July 26, 2004, received July 28, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Novamine 15% Amino Acid Injection.

We acknowledge receipt of your submission dated August 10, 2004.

This new drug application provides for revising the label in order to comply with the requirements of 21 CFR 201.323, along with a test for aluminum determination referenced to a validated analytical method and acceptance criterion of not more than 25 mcg/L of aluminum.

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 submitted labeling (package insert and immediate container and carton labels submitted July 26, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidances for industry titled *Providing Regulatory Submissions in Electronic Format – NDA* and *Providing Regulatory Submissions in Electronic Format-Content of Labeling*. Alternatively, except for the content of labeling, which must be submitted electronically in PDF format, 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 NDA 17-957/S-039**." 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 Sara Stradley, Regulatory Project Manager, at (301) 827-7430.

Sincerely,

{See appended electronic signature page}

Mamta Gautam-Basak, Ph.D.
Chemistry Team Leader II
Division of Metabolic and Endocrine
Drug Products
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Mamta Gautam-Basak
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Approved