DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 07-513/S-024

Hospira, Inc.
Attention: Ms. Melissa A. Nguyen
275 North Field Drive
Bldg H2-2, Dept 0389
Lake Forest, IL 60045-5046

Dear Ms. Nguyen:

Please refer to your supplemental new drug application dated July 31, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Levophed (norepinephrine bitartrate) Injection, 1 mg base/mL.

We acknowledge receipt of your submissions dated June 8, 15, and 22, 2007.

Your submission of June 22, 2007 constituted a complete response to our June 7, 2007 approvable letter.

This supplemental new drug application provides for:

1. Addition of a new glass vial container
for the finished drug product.

2.

3. Revision of the in-process, final release and stability specifications, as appropriate, for the drug product to reflect the change in quantitative composition .

4. Addition of an alternative analytical test method for norepinephrine bitartrate assay in the drug substance and establishment of new analytical test methods for norepinephrine assay and sodium metabisulfite in the finished drug product, Levophed.

5. Revisions to the carton, container, and package insert labeling to reflect the above changes.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the submitted final electronic labeling (package insert and immediate container label submitted June 22, 2007; carton label submitted February 6, 2007**)**.

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

If you have any questions, please contact:

Quynh Nguyen, Pharm.D.
Regulatory Health Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
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/

Norman Stockbridge

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