DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-801/S-034

Hospira, Inc.
Attention: Melissa A. Nguyen
Manager, Regulatory Affairs
275 N. Field Drive
Lake Forest, IL 60045-5046

Dear Ms. Nguyen:

Please refer to your supplemental new drug application dated March 3, 2009 received March 4, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sterile Water for Injection, USP, 1mL.

We acknowledge receipt of your amendment dated June 10, 2009.

This supplemental new drug application provides for the addition of a new fill presentation, specifically 1 mL fill in 2 mL glass flip-top vial, for the drug product at Hospira, Rocky Mount, North Carolina manufacturing facility.

We completed our review of this supplemental new drug application, as amended. This supplement is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below:

Please include the new 1 mL fill presentation in the package insert under the "How Supplied" section.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 18-801/S-034**."

Submit final printed carton and container labels that are identical to the carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 18-801/S-034**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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, call Cathy Tran-Zwanetz, Regulatory Project Manager, at (301) 796-3877.

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/

Jim Vidra

7/2/2009 12:40:00 PM

For Dr. Hasmukh Patel.