DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 62-912/S-038 & S-039

Hospira, Inc.
Attention: Kalpesh Shroff
Manager, Global Regulatory Affairs
Department 0389, Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045-5046

Dear Sir:

This is in reference to your supplemental new drug applications dated November 9, 2007, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), regarding your abbreviated new drug application for Sterile Vancomycin Hydrochloride USP, 1 g (base)/Flip-Top Vial.

Reference is also made to your amendments dated February 21, and September 30, 2008. Reference is also made to the ANDA Suitability Petition (Docket No. 2006P-0533/CP1) submitted under Section 505(j)(2)(c) of the Act and approved on August 22, 2007, permitting you to file these supplemental applications for a drug product that differs in strength (total drug content) from the reference listed product (RLD); i.e. from 1 gram (base)/vial to 750 mg (base)/vial.

The supplemental applications, submitted as "Prior Approval Supplements," provide for the following changes:

S-038: An additional strength of the drug product: Sterile Vancomycin Hydrochloride USP, 750 mg (base)/Flip-Top vial; and

S-039: Revision of the product labeling to reflect the additional strength.

We have completed the review of these supplemental abbreviated applications and have concluded that adequate information has been presented to demonstrate that your Sterile Vancomycin Hydrochloride USP, 750 mg (base)/vial is safe and effective for use as recommended in the submitted labeling. Accordingly, these supplemental applications are approved. The Division of

Bioequivalence has determined that your Sterile Vancomycin Hydrochloride USP, 750 mg (base)/vial, can be expected to have the same therapeutic effect as an equivalent dose of the reference listed drug product upon which the agency relied as the basis of safety and effectiveness.

Post-marketing reporting requirements for these supplemental abbreviated applications are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

The materials submitted are being retained in our files.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
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/

Robert L. West
1/7/2009 12:27:16 PM
Deputy Director, for Gary Buehler