DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-233/S-068

HOSPIRA, Inc.
Att: Ms. Andrea Redd
Senior Associate Global Regulatory Affairs
275 N. Field Drive
D-389, Building H2
Lake Forest, Illinois 60045-5046

Dear Ms. Redd:

Please refer to your supplemental new drug application dated June 29, 2007, received July 2, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sterile Water for Injection, USP, 1000ml.

This supplemental new drug application provide for a modified flexible container referred to as the VisIV™ Flexible IV Container to be manufactured at the Hospira Austin, Texas manufacturing site.

We completed our review of this application. This application 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 submitted on June 29, 2007, and immediate container submitted on June 29, 2007).

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(1) in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Marlène G. Swider, M.H.S.A., Regulatory Project Manager, at (301) 796-2104.

Sincerely,

{See appended electronic signature page}

Daniel A. Shames, M.D.
Acting Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Daniel A. Shames
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