DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-233/S-063

Hospira, Inc.
275 North Field Drive
Dept 389, Bldg H-2
Lake Forest, IL 60045-5046

Attention: Thomas F. Willer, Ph.D.,
Director, Global Regulatory Affairs

Dear Dr. Willer:

Please refer to your supplemental new drug application dated December 29, 2003, received December 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sterile Water for Injection, USP.

Reference is also made to your submissions dated August 20 and September 28, 2004. Your submission dated September 28, 2004, constituted a complete response to our action letter dated June 30, 2004.

This supplemental new drug application provides for a revised immediate container label.

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Pratibha Rana, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthetic, Critical Care, and
Addiction Drug Products
Office of Drug Evaluation II
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/

Bob Rappaport

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