DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019465/S-054
NDA 019466/S-057
NDA 019479/S-049
NDA 019480/S-045
NDA 019759/S-046

SUPPLEMENT APPROVAL

Hospira, Inc.
Attention: Angela LeCaptain
Associate Director, Regulatory Affairs
275 North Field Drive
Dept. 0389, Bldg. H2-2N
Lake Forest, IL 60045-5046

Dear Ms. LeCaptain:

Please refer to your Bundled Supplemental New Drug Application (sNDA) dated and received on April 9, 2014, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for 0.9% Sodium Chloride Injection, USP, in ADD-Vantage, 5% Dextrose Injection, USP in ADD-Vantage, 0.9% Sodium Chloride Injection, USP, 250 mL in ADD-Vantage and 0.45% Sodium Chloride Injection, USP, in ADD-Vantage.

This "Changes Being Effected" supplemental new drug application provides deletion of statement "Only additives in the ADD-Vantage vial should be delivered via this solution" from the Precautions section. The Statement is no longer applicable with the 510(K) clearance of the ADD-Vantage ADDAPTOR™ and a standard flip-top drug vial with 20mm closure. Also changes are being implemented to the How Supplied section to conformity with appropriate NDC format, unit-of-use NDC from the unit-of-sale NDC.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your April 9 2014, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

REPORTING REQUIREMENTS

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 Jacqueline LeeHoffman, Regulatory Project Manager, at (240) 402-8689.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
06/10/2016