DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19480-S46

SUPPLEMENT APPROVAL

Hospira, Inc.
Attention: Laura Kapolnek
Associate, Global Regulatory Affairs
275 North Field Drive
Dept. 0389/Bldg. H2/2N
Lake Forest, IL 60045-5046

Dear Ms. Kapolnek:

Please refer to your Supplemental New Drug Application (sNDA) dated October 3, 2014, received October 3, 2014 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for 0.45% Sodium Chloride Injection, USP, ADD-Vantage® Diluent Flexible Plastic Containers.

This "Changes Being Effected" supplemental new drug application proposes to be consistent with the updates made to Baxter Healthcare Corporations (NDA 018016-S061 and NDA 016677-S147) labeling revisions.

APPROVAL & LABELING

We have completed our review of this supplemental application. 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 October 3, 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 Jaqueline 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
Center for Drug Evaluation and Research

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
09/27/2016