NDA 018916/S-071

GENERAL ADVICE

Hospira Inc.
Attention: Bensheng Liu, PhD
Senior Associate, Global Regulatory Affairs
275 North Field Drive, Bldg. H1-3S
Lake Forest, IL 60045

Dear Dr. Liu:

Please refer to your supplemental new drug application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Heparin Sodium Chloride in 0.45% Sodium Chloride Injection.

We also refer to our approval letter dated July 30, 2020, which contained an error.

The approval letter states the “Changes Being Effected” supplemental new drug application provides for Heparin Sodium in 0.45% Sodium Chloride Injection to align with the USPI for the 0.9% Sodium Chloride Injection presentation.

The correct language for the approval letter should state the “Changes Being Effected” supplemental new drug application provides for Heparin Sodium in 0.45% Sodium Chloride Injection to align with the USPI for the Heparin Sodium in 5% Dextrose presentation.

This General Advice letter acknowledges the error described above and incorporates the correction of the error. The effective approval date will remain July 30, 2020, the date of the original approval letter.

If you have any questions, call Carleveva Thompson, Regulatory Project Manager, at 301-796-1403.

Sincerely,

{See appended electronic signature page}

Ann Farrell, MD
Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology, Endocrinology, and Nephrology
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ANN T FARRELL
08/13/2020 09:44:32 AM

NDA 018916/S-071

SUPPLEMENT APPROVAL

Hospira Inc.
Attention: Bensheng Liu, PhD
Senior Associate, Global Regulatory Affairs
275 North Field Drive, Bldg. H1-3S
Lake Forest, IL 60045

Dear Dr. Liu:

Please refer to your supplemental new drug application (sNDA) dated and received on July 02, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Heparin Sodium Chloride in 0.45% Sodium Chloride Injection.

This "Changes Being Effected" supplemental new drug application provides for revised USPI for Heparin Sodium in 0.45% Sodium Chloride Injection to align with the USPI for the 0.9% Sodium Chloride Injection presentation.

This supplemental new drug application provides for revisions to the labeling for Heparin Sodium Chloride in 0.45% Sodium Chloride Injection.

APPROVAL & LABELING

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

We note that your July 02, 2020, submission includes final printed labeling (FPL) for your Patient Package Insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this FPL 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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling for the Heparin Sodium in 0.45% Sodium Chloride Injection Patient 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. If the content of

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

labeling in SPL format initially submitted with this CBE-0 labeling supplement is identical to the attached approved labeling, an additional submission of content of labeling in SPL format is not required.

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf

[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, call Carleveva Thompson, Regulatory Project Manager, at 301-796-1403.

Sincerely,

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Ann Farrell, MD
Director
Division of Nonmalignant Hematology
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Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Patient Package Insert

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/s/

ANN T FARRELL
07/30/2020 12:27:03 PM