NDAs 18916/S-063, 19339/S-052 and 19805/S-034

APPROVAL LETTER

Hospira, Inc.
Attention: Jae Encarnado
Senior Associate, Pfizer Global Regulatory Affairs
275 North Field Drive, Bldg. H1
Lake Forest, IL 60045

Dear Ms. Encarnado:

Please refer to your supplemental new drug applications (sNDA) dated April 12, 2013, received April 12, 2013, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

APPLICATION NUMBER:	SUPPLEMENT NUMBER:	PRODUCT NAME:
NDA 18916	063	Heparin Sodium in 0.9% or 0.45% Sodium Chloride Injection
NDA 19339	052	Heparin Sodium in 5% Dextrose Injection
NDA 19805	034	Heparin Sodium in 5% Dextrose Injection

We acknowledge receipt of your amendment dated June 13, 2014, which constituted a complete response to our October 3, 2013, action letter.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for updates to the carton and container to present the total strength (potency) per total volume followed by the strength per ml.

APPROVAL & LABELING

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

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, 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 *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, 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).

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 Teicher Agosto, Regulatory Business Process Manager, at (240) 402 - 3777.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling

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

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/

RAMESH RAGHAVACHARI
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