APPROVAL LETTER



NDA 021146/S-025

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

Dear Ms. Rog:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 31, 2020, and your amendment, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Atropine Sulfate Injection, USP.

This Prior Approval supplemental new drug applications provides for Abboject Vial Injector design modification, changes to the carton packaging to open from the top, and carton label and container label modifications.

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.

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(I)] 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 prescribing information) 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 via 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

U.S. Food & Drug Administration Silver Spring, MD 20993 www.fda.gov NDA 021146/S-025 Page 2

action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes, and annotate each change. 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).

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.* For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 021146/S-025.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

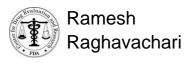
If you have any questions, call Abolade (Bola) Adeolu, Regulatory Business Process Manager, at (301) 796 - 4264.

Sincerely,

{See appended electronic signature page}

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

Enclosures: Content of Labeling



Digitally signed by Ramesh Raghavachari Date: 11/30/2020 02:37:31PM GUID: 502d0913000029f375128b0de8c50020

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