DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21146/S-016

SUPPLEMENT APPROVAL

Hospira, Inc.
Attention: Kristina McIntyre
Product Manager, Global Regulatory Affairs
275 North Field Drive
Dept. 0390, Bldg. H2-2
Lake Forrest, IL 60045

Dear Ms. McIntyre:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 30, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ansyr™ (Atropine Sulfate Injection, USP), 0.1mg/mL and 0.05mg/mL.

In addition to editorial changes made to provide further clarification and increase prominence to improve readability, this Prior Approval supplemental new drug application proposes the following changes:

1) Cartons and Container Labels:
   a) Revised expression of concentration per USP <1>: from 1 mg (0.1 mg/mL) to 1 mg/10 mL (0.1 mg/mL).
   b) Revised "(b) (4)" and "(b) (4)" to "Single-Dose Syringe" per FDA October 2015 guidance titled “Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single- Dose, and Single-Patient-Use Containers for Human Use”.
2) Cartons Labels: Removed (b) (4)

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

We remind you that the Prescribing Information needs to be updated to reflect the changes made to the carton and container labels. Specifically, the following needs to be addressed:

1. DESCRIPTION (Section 11): the reference to pH 4.2 needs to be removed from the last sentence of the second paragraph.

2. HOW SUPPLIED / STORAGE AND HANDLING (Section 16): The first sentence needs to be updated to indicate that Atropine Sulfate Injection, USP is supplied in single-dose "syringes".

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your January 17, 2017, submission containing final printed carton and container labels.

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, please contact Sabry Soukehal, Regulatory Health Project Manager, at (240) 402 6187.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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

/s/

MARY R SOUTHWORTH
01/31/2017