NDA 050609/S-051

SUPPLEMENT APPROVAL

Hospira, Inc.
a Pfizer company
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 November 12, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Erythrocin Lactobionate – IV (erythromycin lactobionate for Injection, USP), 500 mg/vial.

This Prior Approval sNDA provides for updates to the following sections and subsections of the prescribing information (PI): the product title, **DESCRIPTION**, **DOSAGE AND ADMINISTRATION**, **HOW SUPPLIED**; these areas were updated to include "single-dose" descriptor; and the Antimicrobial Activity heading in the **CLINICAL PHARMACOLOGY** section was revised. Additionally, the **DESCRIPTION** section was updated to include an equivalency statement linking the amount of erythromycin free base form to the amount of lactobionate salt form. The **DOSAGE AND ADMINISTRATION** section was also updated to add the statement "discard unused portion" and NEUT™ (4% Sodium Bicarbonate) was removed from under the **Preparation of Solution** subheading. Minor editorial revisions were also made throughout the PI. Carton and Container labeling were also updated to reflect the changes made to the PI.

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 (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 *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).

CARTON AND CONTAINER LABELING

We acknowledge your September 1, 2022, submission containing final printed carton labeling and your November 12, 2021, submission containing final printed container labeling.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

[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.

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 questions, call Sheel Shah, Pharm D, Regulatory Project Manager, at 240-402-3968.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
- Carton and Container Labeling

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/

DMITRI IARIKOV
11/18/2022 02:19:53 PM