DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50609/S-039

SUPPLEMENT APPROVAL

Hospira, Inc. a Pfizer Company
Attention: Maria Hinklin
Associate Director, Pfizer Essential Health Global Regulatory Affairs
275 North Field Drive
Building H1
Lake Forest, IL 60045

Dear Ms. Hinklin:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 20, 2018, 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 supplemental new drug application revises the **CONTRAINDICATIONS** section as suggested in our January 29, 2018, correspondence. The following sentence was added:

Do not use erythromycin concomitantly with 3-hydroxy-3-methylglutaryl-coenzyme A (HMG CoA) reductase inhibitors (statins) that are extensively metabolized by cytochrome P450 isoform 3A4 (lovastatin or simvastatin), due to the increased risk of myopathy, including rhabdomyolysis (see **PRECAUTIONS - Drug Interactions**).

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.
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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. 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 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 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 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).

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, call Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, MD, MPH
Deputy Director of Safety
Division of Anti-Infective Drug Products
Office of Drug Evaluation
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

JOSEPH G TOERNER
04/23/2018