



NDA 50-609/S-025

Hospira, Inc.  
Attention: Melissa A. Nguyen  
Manager, Global Regulatory Affairs  
D-389, Bldg. H2-2N  
275 North Field Drive  
Lake Forest, IL 60045

Dear Ms Nguyen:

Please refer to your supplemental new drug application dated March 29, 2007 and received March 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Erythrocin Lactobionate IV (erythromycin lactobionate for injection USP) 500 mg/vial and 1 g/vial (Fliptop).

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application has been submitted in response to an Agency letter requesting an update to the **WARNINGS** and **PRECAUTIONS** section of the labeling concerning *Clostridium difficile* associated diarrhea.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 29, 2007.

We note that your March 29, 2007 submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
10903 New Hampshire Avenue  
Building 22, Room 4447  
Silver Spring, MD 20903

NDA 50-609  
Page 2

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Katherine A. Laessig, M.D.  
Deputy Director  
Division of Anti-Infective and Ophthalmology Products  
Office of Antimicrobial Products  
Center for Evaluation and Research

Enclosure:

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

/s/

-----  
Kathrine Laessig  
2/26/2008 01:29:25 PM