



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 50-611/032

Abbott, Laboratories  
Attention: Laura L. Granitz, Manager  
Global Pharmaceutical Regulatory Affairs  
Dept. PA 76, Building AP30-1NE  
200 Abbott Park Road  
Abbott Park, IL 60064-6157

Dear Ms. Granitz:

Please refer to your supplemental new drug application dated September 17, 2008, received September 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PCE (erythromycin) Tablet.

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 provides for additional wording to the PRECAUTIONS, **DRUG INTERACTION** section of the labeling regarding erythromycin products and verapamil.

We have completed the review of this application. This application 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 September 17, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling submitted on September 17, 2008. Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved supplemental NDA 50-611/S-0032. Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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/s/

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Kathrine Laessig  
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