DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-611/S-022

Abbott Laboratories
Attention: Mary Konkowski
Manager
Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Dept. RA76, AP30-INE
Abbott, Park, Il 60064-6157

Dear Ms. Konkowski:

Please refer to your supplemental new drug application dated December 30, 2002, received December 31, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PCE Tablets 333 mg and 500 mg (erythromycin particles in tablets).

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

We acknowledge receipt of your submissions dated November 24, 2003 and February 20, 2006.

Your submission of February 20, 2006 constituted a complete response to our May 20, 2004 action letter.

This supplemental new drug application provides for geriatric labeling.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Submit content of labeling [21CFR 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 submitted labeling text dated February 20, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for package insert) submitted February 20, 2006.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 50-611/S-022**." 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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}
Janice M. Soreth
Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug 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/

Janice Soreth

8/9/2006 02:22:49 PM