DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-207/S-068
NDA 50-297/S-030

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 applications dated September 17, 2008, received September 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

E.E.S. 200 Liquid (erythromycin ethylsuccinate for oral suspension) Suspension
E.E.S. 400 Liquid (erythromycin ethylsuccinate for oral suspension) Suspension
E.E.S. Granules (erythromycin ethylsuccinate for oral suspension) Granule, For Suspension
E.E.S. 400 Filmtab Tablets (erythromycin ethylsuccinate tablets) Tablet, Film Coated
Eryped 200 (erythromycin ethylsuccinate) Suspension
Eryped 400 (erythromycin ethylsuccinate) Suspension
Eryped Drops (erythromycin ethylsuccinate) Suspension

These applications are 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 these applications. These applications are 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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that are identical to the enclosed labelings submitted on September 17, 2008. Upon receipt, we will transmit those versions to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions, "SPL for approved supplemental NDAs 50-207/S-068 and 50-297/S-030. Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDAs 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 approved NDAs (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:

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
12/10/2008 11:28:52 AM