



NDA 50-207/S-061
NDA 50-297/S-024
NDA 50-611/S-024

Abbott Laboratories
Attention: MaryClare DeLuca
Project Manager
200 Abbott Park Road
D491, AP30-1E
Abbott Park, IL 60064-6157

Dear Ms.DeLuca:

Please refer to your supplemental new drug applications dated January 26, 2004, received January 27, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

E.E.S.[®] Granules, EryPed[®] Drops, EryPed[®] 200, and EryPed[®] 400 (erythromycin ethylsuccinate for oral suspension, USP) (NDA 50-207),

EryPed[®] Chewable Tablets (erythromycin ethylsuccinate, USP) (NDA 50-297), and

PCE[®] Tablets (erythromycin particles in tablets (NDA 50-611)

We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use" (68FR 6062, February 6, 2003).

We completed the review of these supplemental applications and they are approved effective on the date of this letter for use as recommended in the final printed labeling (FPL) submitted on January 26, 2004.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDA's and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

NDA 50-207/S-061
NDA 50-297/S-024
NDA 50-611/S-024
Page 2

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**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
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