



NDA 50-182/S-125
NDA 50-609/S-019

Abbott Laboratories
Attention: Jeremy Rybicki
Specialist, Regulatory Affairs
200 Abbott Park Road
D-389, J-45-2
Abbott Park, IL 60064-6133

Please refer to your supplemental new drug applications dated February 4, 2004, received February 5, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Erythrocin[®] Lactobionate-IV (erythromycin lactobionate for injection, USP) (NDA 50-182) and Erythrocin[®] Lactobionate-IV (sterile erythromycin lactobionate, USP), (NDA 50-609). 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 "Changes Being Effected" supplemental new drug applications provide for revisions to the package insert to comply with the requirements of the Final Rule, Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use (68FR 6062, February 6, 2003).

We completed our review of these supplemental new drug applications, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 4, 2004.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, MD
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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