DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-182/S-122
NDA 50-609/S-015

Abbott Laboratories
Attention: Jean Kirkeleit-Davis
Manager, Regulatory Affairs
D-389, Bldg. AP 30
Abbott Park, IL 60064-3537

Dear Ms. Kirkeleit-Davis:

Please refer to your supplemental new drug applications dated November 18, 1998, received December 14, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 50-182/S-122, Erythrocin® Piggyback (sterile erythromycin lactobionate), and

NDA 50-609/S-015, Erythrocin Lactobionate-IV (sterile erythromycin lactobionate).

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 geriatric labeling for the package insert.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text with the minor editorial revisions listed below. Accordingly, these supplemental applications are approved effective on the date of this letter.

1. In the **PRECAUTIONS** section, revise the **Geriatric Use** subsection to read as follows:

"**Geriatric Use**:

Elderly patients, particularly those with reduced renal or hepatic function, may be at increased risk for developing erythromycin-induced hearing loss, when Erythrocin® doses of 4 grams/day or higher are given. (See **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION**).

Elderly patients may be more susceptible to the development of torsades de pointes arrhythmias than younger patients. (See **ADVERSE REACTIONS**).

Elderly patients may experience increased effects of oral anticoagulant therapy while undergoing treatment with Erythrocin®. (See **PRECAUTIONS**, Drug Interactions).

Erythromycin Lactobionate does not contain sodium."

2. In the **ADVERSE REACTIONS** section, revise the 2nd sentence of the 4th paragraph, to read as follows.

> "Elderly patients, particularly those with reduced renal or hepatic function, may also be at increased risk for developing this effect, when Erythrocin® doses of 4 grams/day or higher are given. (See **DOSAGE AND ADMINISTRATION**)."

3. In the **DOSAGE AND ADMINISTRATION** section, revise the 2nd sentence of the 1st paragraph, and the 7th paragraph to read as follows.

> "Administration of doses of ≥4 g/day may increase the risk for the development of erythromycin-induced hearing loss in elderly patients, particularly those with reduced renal or hepatic function."

4. In the **REFERENCES** section, revise the 5th reference to read as follows.

> Gitler, B., et al, *Torsades de Pointes Induced by Erythromycin, Chest*, Volume 105: 368-72, February1994.

The final printed labeling (FPL) must be identical as the draft labeling submitted on November 18, 1998, and include the revisions indicated above. These revisions are terms of the approval of these applications.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 50-182/S-122, and 50-609/S-015." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (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 this NDA and a copy to the following address:

MEDWATCH, HF-2
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.

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

Sincerely,

{See appended electronic signature page}

Janice 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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