CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-611/S-018

APPROVAL LETTER

NDA 50-207/S-054
NDA 50-207/S-055
NDA 50-297/S-018
NDA 50-611/S-018

FEB 4 2000

Abbott Laboratories
Attention: Mr. Greg Bosco
PPD Regulatory Affairs
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-3500

Dear Mr. Bosco:

Please refer to your supplemental new drug applications dated May 26, 1999, received May 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ery-Ped® 200 mg and 400 mg (erythromycin ethylsuccinate for oral suspension, USP), NDA 50-207; E.E.S® Granules for Oral Suspension (erythromycin ethylsuccinate for oral suspension, USP), NDA 50-207; Ery-Ped® Chewable Tablets (erythromycin ethylsuccinate tablets, USP), NDA 50-297; P.C.E.® Tablets 333 mg (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.

We also acknowledge receipt of your submissions dated June 4, 1999, received June 7, 1999.

These supplemental new drug applications provide for removal of recommendations by the American Heart Association and the American Dental Association for the use of erythromycin products as prophylaxis of bacterial endocarditis in product labeling. The following changes are noted in the package insert:

> Under **INDICATIONS AND USAGE, Prophylaxis** subsection has been deleted.
> Under **DOSAGE AND ADMINISTRATION, Prophylaxis** subsection has been deleted.
> In the **REFERENCES** section, Reference No. "4" has been deleted.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling (package insert submitted May 26, 1999, and June 4, 1999). Accordingly, the supplemental applications are approved effective on the date of this letter.

Also, we remind you that these labeling changes may apply to any additional erythromycin products not listed in this letter.

Furthermore, the changes approved in these supplements must be implemented within three months from the date of this letter. If you do not implement the above changes within three months, these drug products may be considered misbranded.

Please submit 20 copies of each of the FPLs as soon as they are available, in no case more than 30 days after they are 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 50-207/S-054, NDA 50-207/S-055, NDA 50-297/S-018, and NDA 50-611/S-018." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about these drug products (i.e., a "Dear Health Care Practitioner" 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, Maryland 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.8 1.

If you have any questions, please call CDR Jose R. Cintron, USPHS. Senior Regulatory Management Officer/ Project Manager, at (301) 827-2125.

Sincerely yours,

/S/

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL