# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

# 50-611/S-018

# ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEC 3 1999

# PROJECT MANAGER REVIEW OF SUPPLEMENTS

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

**DATE OF SUBMISSION:** **June 4, 1999**

**DATE REVIEW STARTED:** **December 3, 1999**

**DATE REVIEW COMPLETED:** **December 3, 1999**

**APPLICANT:** **Abbott Laboratories**

**PRODUCT NAME (S):** Ery-Ped® 200 mg and 400 mg (erythromycin ethylsuccinate for oral suspension, USP)

E.E.S® Granules for Oral Suspension (erythromycin ethylsuccinate for oral suspension, USP)

Ery-Ped® Chewable Tablets (erythromycin ethylsuccinate tablets, USP)

P.C.E.® Tablets 333 mg (erythromycin particles in tablets)

**GENERIC NAME:** **Erythromycin**

**CATEGORY:** **Macrolides**

**DOSAGE FORM AND ROUTE OF ADMINISTRATION: Tablets, Oral Suspension**

**MATERIALS SUBMITTED:**

Agency letter dated February 26, 1999; marked-up copy of labeling highlighting the changes requested in our letter; and draft labeling incorporating the requested changes.

**PURPOSE OF SUPPLEMENTS:**
The firm's response to our February 26, 1999 letter requesting the removal of recommendations by the American Heart Association (AHA) and the American Dental Association (ADA) for the use of erythromycin products as prophylaxis of bacterial endocarditis in product labeling.

**DISCUSSION:**

As contained in the submissions dated May 26, 1999, and June 4, 1999, the proposed labeling revisions reviewed below are for the erythromycins:

Under the **INDICATION AND USAGE** section, Prophylaxis subsection has been deleted.

*Comment:* The deletion is in compliance with our request.

Under the **DOSAGE AND ADMINISTRATION** section, Prophylaxis subsection has been deleted.

*Comment:* The deletion is in compliance with our request.

In the **REFERENCES** section, Reference No. "4" has been deleted.

*Comment:* The deletion is in compliance with our request.

**ACTION RECOMMDATIONS:**
It is recommended that these supplemental applications be approved. The sponsor should be notified to submit final printed labeling containing all the changes proposed in these supplements within three months. The above labeling recommendation should be conveyed to the sponsor in the approval letter for these supplements.

/S/

Jose R. Cintron, R.Ph., M.A.
Senior Regulatory Management Officer

/S/

Nasim Moledina, M.D.
Clinical Reviewer

/S/

Mercedes Albueme, M.D.
Clinical Team Leader

APPEARS THIS WAY
ON ORIGINAL

ABBOTT

ORIGINAL
SLR-018

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108
May 26, 1999

NDA NO. 50611 SUPPL. NO. S-018
NDA SUPPL. TYPE SLR

RECD
MAY 27 1999
MEGA DOCUM
EVALUATION AND RESEARCH

Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850

**Re: PCE® Tablets, 333 mg (List No. 6290) and 500 mg (List No. 3389)**
**(erythromycin particles in tablets)**
**NDA 50-611**

**DRAFT LABELING**

Dear Sir or Madam:

The sponsor, Abbott Laboratories, submits this supplement to an Abbreviated New Drug Application under the provisions of Section 507 of the Federal Food, Drug and Cosmetic Act and CFR 314.70(c).

The purpose of this supplement is to submit draft labeling for PCE reflecting revisions requested in correspondence, dated February 26, 1999, from Dr. Chikami of the Division of Anti-Infective Drug Products.

Should you have any questions concerning this submission, or need any additional information, please contact me at the number provided below.

Sincerely,

Matthew Biondi
Senior Regulatory Specialist
PPD Regulatory Affairs
(847) 938-0623

APPEARS THIS WAY
ON ORIGINAL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-611/S-018

Abbott Laboratories
D-491/AP6B-1 100 Abbott Park Road
Abbott Park, IL 60064-3500

JUN 3 1999

Attention: Mathews Biondi
Sr. Reg. Affairs Specialist

Dear Mr. Biondi:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: PCE (erythromycin particles) Tablets

NDA Number: 50-611

Supplement Number: S-018

Date of Supplement: May 26, 1999

Date of Receipt: May 27, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on July 26, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Infective Drug Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/S/

James D. Bona, R.Ph., M.P.H.
Chief, Project Management Staff
Division of Anti-Infective Drug Products, HFD-520
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ABBOTT

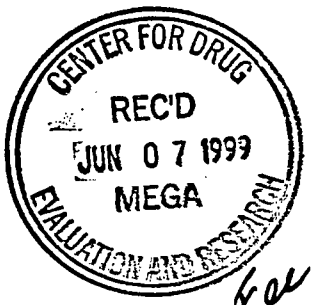
SUPPL NEW CORRESP

SNC - 018

Pharmaceutical Products Division

Abbott Laboratories
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

June 4, 1999




Division of Anti-Infective Drug Products, HFD-520
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
1st Floor Document Control Room
Rockville, Maryland 20850

contains User Fee Cover Sheet

S106/08/99

**Re: PCE® Tablets, 333 mg (List No. 6290) and 500 mg (List No. 3389)**
**(erythromycin particles in tablets)**
**NDA 50-611 Supplement (S-018)**

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Should you have any questions concerning this submission, or need any additional information, please contact me at the number provided below.

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ORIGINAL