CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-207/S-054, S-055

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DivFile 50-297

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

cc:
HFD-520 Div.Files
HFD-520
HFD-520/TL/MO/MAlbuerne
HFD-520/MO/NMoledina
HFD-613/OGD/CHoppes
HFD-613/OGD/Jwhite
HFD-520/PMS/JCintron

Concurrence only:
HFD-520/C/PMS/FLeSane
HFD-520/DD/GChikatni

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DIV

Food and Drug Administration
Rockville MD 20857

NDA 50-207/S-055

Abbott Laboratories
D-491/AP6B-1 100 Abbott Park Road
Abbott Park, IL 60064-3500
Attention: Mathew Biondi
Sr. Reg. Affairs Specialist

JUN 3 1999

Dear Mr. Biondi:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: E.E.S. Granules (erythromycin ethylsuccinate) Oral Suspension

NDA Number: 50-207

Supplement Number: S-054

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,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-207/S-054

Abbott Laboratories
D-491/AP6B-1 100 Abbott Park Road
Abbott Park, IL 60064-3500
Attention: Mathew Biondi
Sr. Reg. Affairs Specialist

JUN 3 1999

Dear Mr. Biondi:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: EryPed® 200, EryPed® 400, EryPed® Drops (erythromycin ethylsuccinate) Oral Suspension

NDA Number: 50-207

Supplement Number: S-054

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:

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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