

**CENTER FOR DRUG EVALUATION AND RESEARCH**

***APPLICATION NUMBER:***

**50-207/S-054, S-055**

**ADMINISTRATIVE DOCUMENTS**  
**AND**  
**CORRESPONDENCE**

Div File

50-897

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.

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**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 RECOMMENDATIONS:**

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/**

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Nasim Moledina, M.D.  
Clinical Reviewer

**/S/**

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Mercedes Albueme, M.D.  
Clinical Team Leader

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cc:

HFD-520 Div.Files

HFD-520

HFD-520/TL/MO/MAIbuerne *mlh 1/2/00*

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  
*mlh 1/2/00*



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

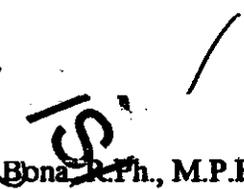
Date of Receipt: May 27, 1999

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



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).

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Office of Drug Evaluation IV  
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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