CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-662/A029

CORRESPONDENCE

ABBOTT

Pharmaceutical Products Division

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

December 17, 1999

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

Re: BIAXIN® FILMTAB®
(clarithromycin tablets)
NDA 50-662
Supplement 029

EFFICACY SUPPLEMENT

Dear Sir or Madam:

The sponsor. Abbott Laboratories. submits this supplement to a New Drug Application under the provisions of Section 505(1) of the Federal Food. Drug and Cosmetic Act and 21 CFR 314.70(b)(3).

The purpose of this supplement is to add the microorganism *Haemophilis influenzae* to the previously approved indication of Community-Acquired Pneumonia. The information provided in this supplement supports this change in labeling.

To aid in the review of this supplement. please find:

1. FDA Forms (356h. User Fee. Debarment Certification. Financial Disclosure. prior FDA Correspondence).

2. Request for waiver of pediatric study requirement (21 CFR 314.55(c)(2).

3. Draft labeling incorporating changes to the Indications and Dosage and Administration sections. The draft labeling is also being provided on diskette. Please note. this file was created and saved in Word Perfect 6.1. Only one FDA copy will include the diskette.

4. Clinical study summary report for one clarithromycin clinical study, M98-927. entitled "Comparison of the Safety and Efficacy of Clarithromycin IR (250 mg BID) or ER (1000 mg QD) to Trovafloxacin (200 mg QD) for the Treatment of Community-Acquired Pneumonia".

APPEARS THIS WAY
ON ORIGINAL

Should you have any questions regarding this information, or need any additional information, please do not hesitate to call me at the number listed below. Thank you for your consideration in this matter.

Sincerely,

/S/

Greg Bosco
Sr. Product Manager
PPD Regulatory Affairs
(847) 937-6970

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-662/S-029

Abbott Laboratories
Attention: Greg Bosco
Product Manager, 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 application dated December 17, 1999, received December 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Biaxin® Filmtab® (clarithromycin tablets) USP. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application provides for the addition of *Haemophilus influenzae* to the previously approved indication of Community-Acquired Pneumonia for Biaxin Filmtab (clarithromycin tablets).

We have completed the review of your revised labeling for this supplemental application originally approved with modifications on October 20, 2000. In response to your inquiries submitted to the Division on October 26, 2000, the labeling has been further revised. As agreed at the teleconference between you and Mr. Jose R. Cintron on November 1, 2000, the attached label dated October 31, 2000, is the final label for this supplement.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-662/S-029." Approval of this submission by FDA is not required before the labeling is used.

The final printed labeling (FPL) must be identical to the draft labeling dated October 31, 2000, attached in this letter.

If you have any questions, call CDR. Jose R. Cintron, USPHS, Senior Regulatory Management Officer, at 301-827-2125.

Sincerely,

Janice Soreth, M.D.
Acting Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research