CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-662/A029

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 20 2000

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). 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.

We acknowledge receipt of your submissions dated February 14, 2000; March 13, 2000; May 1, 2000; and May 23, 2000.

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 this supplemental application, as amended, 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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling dated October 12, 2000, provided in this letter.

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.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632)(21 CFR 314.55 (or 601.27)).

Reference is made to your correspondence dated December 17, 1999, requesting a waiver for pediatric studies under 21 CFR 314.55(c). We have reviewed the information you have submitted and agree that a waiver is justified for Biaxin Filmtab (clarithromycin tablets) for Community-acquired pneumonia for the pediatric population. Accordingly, a waiver for pediatric studies for this application is granted under 21 CFR 314.55 at this time. We note that you have satisfied the pediatric study requirements for this action on your approved pediatric dosage form of clarithromycin (Biaxin Granules) for NDA 50-698, which is already labeled for Community-Acquired Pneumonia.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (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, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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

Sincerely,

/S/

10/19/05

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