NDA 50-775

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 new drug application (NDA) dated April 30, 1999, received May 3, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BIAXIN® XL Filmtab® (clarithromycin extended release tablets).

We acknowledge receipt of your submissions dated August 4, 1999, September 4, October 26, December 3, 1999; February 7, February 24, February 25, March 2, and March 3, 2000.

This new drug application provides for the use of BIAXIN® XL®Filmtab (clarithromycin extended release tablets) Tablets for Acute Bacterial Exacerbation of Chronic Bronchitis (AECB) and Acute Maxillary Sinusitis.

We have completed the review of this 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 enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

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). We are waiving the pediatric study requirement for this action on this application. The waiver has been granted for these two indications on the basis of the information contained in your August 4, 1999 waiver request. Specifically for AECB you provided two expert guidance to corroborate that AECB is not a disease occurring in the pediatric population. For Acute Maxillary Sinusitis, which affects patients of all ages groups, this particular dosage form does not represent a meaningful therapeutic benefit over existing treatments and would not be used in a substantial number of pediatric patients. The approved pediatric dosage form of clarithromycin (Biaxin Granules) is already labeled for sinusitis, and the dose and tablet size of the BIAXIN® XL dosage form (500 mg) is too large to be acceptable for use in young children. BIAXIN® XL 500 mg is an alternative dosage form for children 12 years old and older. In addition you have documented attempts to develop a pediatric extended released formulation.

We remind you of your commitments agreed on March 2, 2000 teleconference, to place three production batches of the drug product and the related drug substance lots on stability study. The stability study should consist of at least one lot of the drug product in each container type proposed in this application. Place the drug substance lots on stability in the approved container . The results of these studies should be reported in the annual reports. For details please refer to Attachment 1.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels) to the final labeling dated March 3, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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 heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 50-775." Approval of this submission by FDA is not required before the labeling is used.

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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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/Project Manager, at (301) 827-2125.

Sincerely,

Gary K. Chikami M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV

Center for Drug Evaluation and Research

Enclosure