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RESEARCH**

APPLICATION NUMBER:

50-775/S001

APPROVAL LETTER



NDA 50-775/S-001

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 September 29, 2000, received October 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for **BIAXIN® XL Filmtab®** (clarithromycin extended release 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 also acknowledge receipt of your submissions dated March 22, 2001 and June 20, 2001.

This supplemental new drug application provides for addition of Community-Acquired Pneumonia due to *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Moraxella catarrhalis*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Chlamydia pneumonia* (TWAR), *Legionella pneumophila* or *Mycoplasma Pneumoniae* to the **BIAXIN® XL Filmtab®** label.

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 in Community-Acquired Pneumonia due to the aforementioned microorganisms except *Legionella pneumophila* and *Staphylococcus aureus*. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the attached draft revised package insert dated August 1, 2001. These revisions are terms of the approval of this application.

Please submit a copy of the final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-775/S-001." Approval of this submission by FDA is not required before the labeling is used.

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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.

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 Professional" 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 Jose R. Cintron, R.Ph., M.A., Sr. Regulatory Management Officer/Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

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