DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-662/S-036
NDA 50-697/S-003
NDA 50-698/S-019
NDA 50-775/S-007

Abbott Laboratories
Attention: MaryClare DeLuca
Project Manager
200 Abbott Park Road
D491, AP30-1E
Abbott Park, IL 60064-6517

Dear Ms.DeLuca:

Please refer to your supplemental new drug applications listed below, dated February 2, 2004, received February 3, 2004, which were submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act:

NDA #	**Drug Product**	**Supplement Number**
50-662	Biaxin® Filmtabs® (clarithromycin tablets, USP)	S-036
50-697	Biaxin® (clarithromycin) for MAC Treatment	S-003
50-698	Biaxin® Granules (clarithromycin for Oral Suspension, USP)	S-019
50-775	Biaxin® XL Filmtabs® (clarithromycin extended-release tablets)	S-007

We acknowledge receipt of your submissions dated March 8 and March 23, 2004.

These "Changes Being Effected" supplemental new drug applications provide for revised labeling to comply with the Final Rule entitled "**Labeling Requirements for Systemic Antimicrobial Drug Products Intended for Human Use"** (68FR 6062, February 6, 2003) and respond to our CBE request letter dated September 11, 2003.

These "Changes Being Effected" supplemental new drug applications provide for the following additions to the package insert:

Location	Added text
At the beginning of the label, under "**PRODUCT NAME"**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of BIAXIN and other antibacterial drugs, BIAXIN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
INDICATIONS AND USAGE section, under "Prophylaxis" subsection	To reduce the development of drug-resistant bacteria and maintain the effectiveness of BIAXIN and other antibacterial drugs, BIAXIN should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
PRECAUTIONS section, under "General" subsection	Prescribing BIAXIN in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication it is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.
PRECAUTIONS section, under "Information for patients"	Patients should be counseled that antibacterial drugs including BIAXIN should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When BIAXIN is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by BIAXIN or other antibacterial drugs in the future.

In addition, the following revisions to the package insert were noted (additions are double underlined and deletions are in strikethrough):

- In the **"DOSAGE AND ADMINISTRATION"** section, the following sentence was revised:

  BIAXIN ~~®~~ XL tablets ~~Filmtab®~~ should be swallowed whole and not chewed, broken, or crushed.

- In the "Duodenal Ulcer Associated with *H. pylori* Infection; Clarithromycin + Lansoprazole and Amoxicillin" subsection of the **"CLINICAL STUDIES"** section, the following sentences were revised:

  Triple therapy: BIAXIN (clarithromycin) 500 mg b.i.d. + lansoprazole 30 mg b.i.d. + amoxicillin 1 gm b.i.d.

The combination of BIAXIN ~~(clarithromycin)~~ plus lansoprazole and amoxicillin as triple therapy was effective in eradicating *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence.

We have completed the review of these supplemental applications, 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 final printed label submitted on February 2, 2004 (enclosed). Accordingly, these supplemental applications are approved effective on the date of this letter.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Kristen Miller, Pharm.D., Project Manager at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Renata Albrecht

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