CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-775/S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-775/S-004

Abbott Laboratories
Attention: Greg Bosco
Sr. Product Manager
D-491/AP 6B-1SW
100 Abbott Park Road
Abbott Park, IL 60064-6108

Dear Mr. Bosco:

Please refer to your supplemental new drug application dated July 17, 2001, received July 18, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Biaxin ® XL Filmtab ® (clarithromycin extended-release tablets), 500 mg.

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 "Changes Being Effected" supplemental new drug application provides for revisions to the **ADVERSE REACTIONS,** *Post-Marketing Experience* and **DOSAGE AND ADMINISTRATION** sections of the package insert.

We have completed our review of this supplemental application, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted on July 17, 2001.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may 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. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-775/S-004." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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, call Judit Milstein, Regulatory Project Manager, at (301) 827-2207.

Sincerely,

{See appended electronic signature page}

Janice M.Soreth, MD
Director
Division of Anti-Infective 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/

Janice Soreth
4/11/03 04:25:13 PM

APPEARS THIS WAY
ON ORIGINAL