DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-662/S-038
NDA 50-698/S-020
NDA 50-775/S-008

Abbott Laboratories
Attention: Mary Clare De Luca
Project Manager
200 Abbott Park Road
RA 76 AP30-INE
Abbott Park, Illinois 60064-6157

Dear Ms DeLuca:

Please refer to your supplemental new drug applications dated February 10, 2005, received February 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Biaxin Filmtabs (clarithromycin tablets), NDA 50-662/S-038, Biaxin Granules (clarithromycin oral suspension), NDA 50-698/S-020 and Biaxin XL Filmtabs (clarithromycin extended release tablets), NDA 50-775/S-008.

This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These supplemental new drug applications provide for revisions to the Contraindications, Precautions-Drug Interactions and Adverse Reactions-Post Marketing Experience sections of the labeling.

We completed our review of these applications. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted February 10, 2005.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions **"FPL for approved supplements"** NDA 50-662/S-038, NDA 50-698/S-020 and NDA 50-775/S-008. Approval of these submissions 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, 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, call Carmen DeBellas, Regulatory Project Manager, at (301)796-1203.

Sincerely,

{See appended electronic signature page}

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

Enclosure:

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

10/4/2005 12:22:23 PM