DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-662/S-041
NDA 50-698/S-023
NDA 50-775/S-012

Abbott Laboratories
Attention: Mary Konkowski
Manager, Global Pharmaceutical Regulatory Affairs
Dept. RA 76/Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, Il 60064-6157

Dear Ms Konkowski:

Please refer to your supplemental new drug applications dated April 27, 2007, received April 30, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 50-662 Biaxin® Filmtabs® (clarithromycin tablets)
NDA 50-698 Biaxin® Granules ® (clarithromycin for oral suspension)
NDA 50-775 Biaxin® XL Filmtabs® (clarithromycin extended-release tablets)

These applications are 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 the addition of new information related to myasthenia gravis in the **PRECAUTIONS – General** section of the labeling.

We have completed the 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 packaging insert).

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 copies of the FPL on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplements NDA 50-662/S-041, NDA, 50-698/S-023 and NDA 50-775/S-012"** 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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

If you have any questions, call Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy 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/

Kathrine Laessig
5/22/2008 10:46:22 AM