DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-662/S-044 and S-050
NDA 50-698/S-026 and S-030
NDA 50-775/S-015 and S-019

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Viraj B. Gandhi
Manager, Regulatory Affairs- PPG
Dept. PA77, Bldg. AP30-LL
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Mr. Gandhi:

Please refer to your Supplemental New Drug Applications (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug Name	NDA #/Supplement	Submitted Date	Received Date
Biaxin Filmtabs (clarithromycin tablets, USP)	NDA 50-662/S-044	10/31/08	11/03/08
Biaxin Granules (clarithromycin for oral suspension, USP)	NDA 50-698/S-026	10/31/08	11/03/08
Biaxin XL Filmtabs (clarithromycin extended release tablets)	NDA 50-775/S-015	10/31/08	11/03/08
Biaxin Filmtabs (clarithromycin tablets, USP)	NDA 50-662/S-050	01/10/12	01/10/12
Biaxin Granules (clarithromycin for oral suspension, USP)	NDA 50-698/S-030	01/10/12	01/10/12
Biaxin XL Filmtabs (clarithromycin extended release tablets)	NDA 50-775/S-019	01/10/12	01/10/12

The "Prior Approval" supplemental new drug applications submitted on October 31, 2008, provide for revisions to the package insert to change information for *in vitro* susceptibility test interpretive criteria (breakpoints) and quality control parameters for the *in vitro* susceptibility testing of organisms.

The "Prior Approval" supplemental new drug applications submitted on January 10, 2012, provide for the addition of a **QT Prolongation** subsection to the **WARNING s**ection of the label and addition of a statement regarding development of torsades de pointes arrhythmias to the Geriatric Use section as requested in the Agency letter dated November 15, 2011.

We acknowledge receipt of your amendment(s) dated June 15, and December 9, 2011, and February 15, and April 23, 2012 to the October 31, 2008, supplements. Your submission of June 15, 2011, constituted a complete response to our January 21, 2011, action letter.

Additionally, we acknowledge receipt of your amendment(s) dated April 24, 2012, to the January 10, 2012 supplements.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions indicated (underlined) in the enclosed labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling for the package insert, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement numbers and annual report dates.

REPORTING REQUIREMENTS

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}

Sumathi Nambiar, MD, MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

SUMATHI NAMBIAR
05/03/2012