DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

SUPPLEMENT APPROVAL

NDA 50-662/S-043
NDA 50-662/S-045
NDA 50-698/S-025
NDA 50-698/S-027
NDA 50-775/S-014
NDA 50-775/S-016

Abbott Laboratories,
Attention: Richard Leber
Manager, Global Pharmaceutical Regulatory Affairs
PA76, AP30-1
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Mr. Leber:

Please refer to your Supplemental New Drug Applications (sNDA) dated September 25, 2008, received September 26, 2008 and November 24, 2009, received November 25, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

Drug Name	NDA #/Supplement	Received Date	Received Date
Biaxin Filmtabs (clarithromycin tablets, USP)	NDA 50-662/S-043	9-25-08	
Biaxin Filmtabs (clarithromycin tablets, USP)	NDA 50-662/S-045		11-25-09
Biaxin Granules (clarithromycin for oral suspension, USP)	NDA 50-698/S-025	9-25-08	
Biaxin Granules (clarithromycin for oral suspension, USP)	NDA 50-689/S-027		11-25-09
Biaxin XL Filmtabs (clarithromycin extended release tablets)	NDA 50-775/S-014	9-25-08	
Biaxin XL Filmtabs (clarithromycin extended release tablets)	NDA 50-775/S-016		11-25-09

We acknowledge receipt of your amendments dated May 16, 2011.

The November 19, 2010, submission constituted a complete response to our July 14, 2010, action letter issued for supplements S-043, S-025 and S-014.

The supplemental applications submitted on September 25, 2008, were "Changes Being Effected" supplemental new drug applications and provided for changes to the **PRECAUTIONS- Drug Interactions** subsection and **ADVERSE REACTIONS- Post-Marketing Experience** subsection of the labeling.

NDA 50-662/S-043
NDA 50-662/S-045
NDA 50-698/S-025
NDA 50-698/S-027
NDA 50-775/S-014
NDA 50-775/S-016

The supplemental applications submitted on November 24, 2009 were "Prior Approval" supplemental new drug applications and provided the study report for a renal impairment study supporting dosage adjustment of clarithromycin in patients with renal impairment.

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.

We note that your May 16, 2011, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 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 this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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 number(s) and annual report date(s).

NDA 50-662/S-043
NDA 50-662/S-045
NDA 50-698/S-025
NDA 50-698/S-027
NDA 50-775/S-014
NDA 50-775/S-016

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to these NDAs to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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(S):
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
05/27/2011