DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-662/S-046
NDA 50-698/S-028
NDA 50-775/S-017

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Judith Hoenig
Manager, Regulatory Affairs- CMC
Dept. PA71, Bldg. AP30
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Hoenig:

Please refer to your Supplemental New Drug Applications (sNDA) dated April 15, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50-662/S-046	Biaxin Filmtabs (clarithromycin tablets, USP)
NDA 50-698/S-028	Biaxin Granules (clarithromycin for oral suspension, USP)
NDA 50-775/S-017	Biaxin XL Filmtabs (clarithromycin extended release tablets)

The March 1, 2012, submission constituted a complete response to our March 21, 2011, action letter.

These “Prior Approval” supplemental new drug applications propose to standardize Biaxin package labeling in accordance with Abbott Laboratories' plan to standardize package labeling for its pharmaceutical products.

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon carton and container labeling text.

We acknowledge your March 1, 2012, submission containing final printed carton and container labels.

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):
Carton and container 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
06/01/2012