DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-662/S-042
NDA 50-698/S-024
NDA 50-775/S-013

APPROVAL LETTER

Abbott Laboratories
Attention: Kevin Fitzpatrick
Director, North American Regulatory Affairs
200 Abbott Park Rd.
RA76 AP30-INE
Abbott Park, IL 60064-6157

Dear Mr. Fitzpatrick:

Please refer to your supplemental new drug applications dated November 1, 2007, received November 2, 2007, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA 50-662 Biaxin® Filmtabs®
NDA 50-698 Biaxin® Granules
NDA 50-775 Biaxin® XL Filmtabs®

These supplemental new drug applications provide for changes to the **ADVERSE REACTIONS - Post-Marketing** section to add information on loss of smell to the label.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 1, 2007.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to enclosed labeling (text for package insert) submitted November 1, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "**SPL for approved supplemental NDA 50-662/S-042, NDA 50-698/S-24 and NDA 50-775/S-013).**"

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

We remind you that you must comply with the requirements for an approved NDA set forth under 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}

Katherine A. Laessig, MD
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

KATHERINE A LAESSIG
08/14/2009