



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

NDA 50662/S-060  
NDA 50698/S-040  
NDA 50775/S-028

**SUPPLEMENT APPROVAL**

Abbvie, Inc.  
Attention: Aansh Jarmarwala  
Director, Regulatory Affairs  
1 North Waukegan Road, Dept. PA77/Bldg. AP30  
North Chicago, IL 60064

Dear Dr. Jarmarwala:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 28, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA 50662/S-060 Biaxin Filmtab (clarithromycin tablets, USP)  
NDA 50698/S-040 Biaxin Granules (clarithromycin for oral suspension, USP)  
NDA 50775/S-028 Biaxin XL Filmtab (clarithromycin extended-release tablets)

These Prior Approval supplemental new drug applications have been submitted in response to the Pregnancy and Lactation Rule (PLLR) published in the Federal Register in December 2014, "Content and Format of Labeling Rule for Human Prescription Drug and Biological Products: Requirements for Pregnancy and Lactation Labeling," 79 FR 233, December 4, 2014. And 21 CFR 201.56(a and d) and 201.57 (c) (9) (I, ii, and iii) updating **Section 8 USE IN SPECIFIC POPULATIONS** specifically, **sub-sections 8.2 Lactation** and **8.3 Nursing Mothers**.

**APPROVAL & LABELING**

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

**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 text for the Prescribing Information, 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 that include labeling changes for this NDA, 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

### **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 Christopher L. Smith PharmD, MPH, Regulatory Project Manager, at (301) 796-4851.

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infective Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):  
Content of Labeling  
Prescribing Information

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**  
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/s/  
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DMITRI IARIKOV  
12/19/2018