



NDA 50-662/S-059  
NDA 50-698/S-039  
NDA 50-775/S-027

## SUPPLEMENT APPROVAL

AbbVie, Inc  
Attention: Aansh Jarmarwala, PharmD, RAC  
Senior Manager, Global Regulatory Strategy  
1 North Waukegan Road  
North Chicago, IL 60064

Dear Dr. Jarmarwala:

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 27, 2018, received April 27, 2018 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

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

These supplemental applications propose changes under **WARNINGS AND PRECAUTIONS** section (5) to **QT Prolongation** subsection (5.2) and **Serious Adverse Reactions Due to Concomitant Use with Other Drugs** subsection (5.4). In addition, the Applicant has revised under **CLINICAL PHARMACOLOGY** section (12) the **Microbiology** subsection (12.4) and **REFERENCE** section (15) in response to the Agency letter dated February 23, 2018 regarding new Interpretive criteria web page.

### **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, 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  
11/25/2018