



NDA 50662/S-058
NDA 50698/S-038
NDA 50775/S-026

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: Robert J. Baker
Senior Manager, Regulatory Affairs – USA & Canada
1 North Waukegan Road, Dept. PA77/Bldg. AP30
North Chicago, IL 60064

Dear Mr. Baker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received February 1, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50662- Biaxin Filmtabs (clarithromycin tablets, USP),
NDA 50698- Biaxin Granules (clarithromycin for oral suspension, USP)
NDA 50775- Biaxin XL Filmtabs (clarithromycin extended release tablets)

These Prior Approval supplemental new drug applications revise the labeling to include safety information about risk of all-cause mortality in patients with coronary artery disease 1 to 10 years after Biaxin exposure, and acute generalized exanthematous pustulosis (AGEP), as indicated below:

WARNINGS AND PRECAUTIONS section, addition of AGEP to the **Acute Hypersensitivity (5.1)** subsection and addition of **All-Cause Mortality in Patients with Coronary Artery Disease 1 to 10 Years After BIAXIN Exposure (5.5)** subsection.

ADVERSE REACTIONS section, addition of the summary safety data from a clinical trial in patients with coronary artery disease to the **Clinical Trials Experience (6.1)** subsection.

PATIENT COUNSELING INFORMATION (17) section, addition of information to provide to patients with coronary artery disease.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended, and 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:

NDA 50662/S-058
NDA 50698/S-038
NDA 50775/S-026
Page 2

<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Content of labeling must be identical to the enclosed labeling 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 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).

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 Susmita Samanta, Safety Regulatory Project Manager, at (301) 796-0803.

Sincerely,

{See appended electronic signature page}

Joseph Toerner, M.D., M.P.H.
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
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/

JOSEPH G TOERNER
06/09/2017