NDA 50662/S-061
NDA 50698/S-041
NDA 50775/S-029

SUPPLEMENT APPROVAL

Abbvie, Inc.
Attention: Aansh Jarmarwala, PharmD, RAC
Senior Manager, Global Regulatory Strategy
1 North Waukegan Road, Department. PA77/Building AP30
North Chicago, IL 60064

Dear Dr. Jarmarwala:

Please refer to your supplemental new drug applications (sNDAs) dated February 07, 2019, received February 07, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 50662/S-061 Biaxin Filmtab (clarithromycin tablets for oral use)
NDA 50698/S-041 Biaxin Granules (clarithromycin for oral suspension)
NDA 50775/S-029 Biaxin XL Filmtab (clarithromycin extended-release tablets for oral use)

These Prior Approval supplemental new drug applications provide for the addition of a drug-drug interaction between clarithromycin and lomitapide to the **CONTRAINDICATIONS (4)** section, **Lomitapide, Lovastatin, and Simvastatin (4.5)** subsection, **WARNINGS AND PRECAUTIONS (5)** section, **Serious Adverse Reactions Due to Concomitant Use with Other Drugs (5.4)** subsection, and **DRUG INTERACTIONS (7)** section of the labeling.

APPROVAL & LABELING

We have completed our review of these 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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling text for the

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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 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

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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.

/s/

DMITRI IARIKOV
09/18/2019 10:28:52 AM