DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

**NDA 50-662/S-052**
**NDA 50-662 S-053**
**NDA 50-698/S-031**
**NDA 50-698/S-032**
**NDA 50-775/S-020**
**NDA 50-775/S-021**

**SUPPLEMENT APPROVAL**

Abbvie, Inc.
Attention: Viraji B. Gandhi
Manager, Regulatory Affairs-PPG
3 North Waukegan Road
North Chicago, IL 60064

Dear Mr. Gandhi:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 29, 2012, received March 29, 2012 and October 24, 2012, received October 24, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

| Drug Name | NDA #/Supplement | Received Date |
|---|---|---|
| Biaxin Filmtabs (clarithromycin tablets, USP) | NDA 50-662/S-052 | 3-29-12 |
| Biaxin Filmtabs (clarithromycin tablets, USP) | NDA 50-662/S-053 | 10-24-12 |
| Biaxin Granules (clarithromycin for oral suspension, USP) | NDA 50-698/S-031 | 3-29-12 |
| Biaxin Granules (clarithromycin for oral suspension, USP) | NDA 50-689/S-032 | 10-24-12 |
| Biaxin XL Filmtabs (clarithromycin extended release tablets) | NDA 50-775/S-020 | 3-29-12 |
| Biaxin XL Filmtabs (clarithromycin extended release tablets) | NDA 50-775/S-021 | 10-24-12 |

We acknowledge receipt of the following amendments:

| Drug Name | NDA #/Supplement | Received Date |
|---|---|---|
| Biaxin Filmtabs (clarithromycin tablets, USP) | NDA 50-662/S-052 | 7-30-12<br>8-14-13 |
| Biaxin Filmtabs (clarithromycin tablets, USP) | NDA 50-662/S-053 | 8-14-13 |
| Biaxin Granules (clarithromycin for oral suspension, USP) | NDA 50-698/S-031 | 7-30-12<br>8-14-13 |
| Biaxin Granules (clarithromycin for oral suspension, USP) | NDA 50-689/S-032 | 8-14-13 |
| Biaxin XL Filmtabs (clarithromycin extended release tablets) | NDA 50-775/S-020 | 7-30-12<br>8-14-13 |
| Biaxin XL Filmtabs (clarithromycin extended release tablets) | NDA 50-775/S-021 | 8-14-13 |

These "Prior Approval" supplemental new drug applications provide for the following:

Supplemental applications NDA 50-662/S-052, NDA 50-698/S-031, and NDA 50-775/S-020 provide for revised labeling to update the PRECAUTIONS Section, Nursing mothers and Drug Interactions subsections, DOSAGE and ADMINISTRATION Section, WARNINGS Section, and the ADVERSE REACTIONS Section of the package insert.

Supplemental applications NDA 50-662/S-053, NDA 50-698/S-032, and NDA 50-775/S-021 provide revised labeling to update the ADVERSE REACTIONS Section, postmarketing experience subsection of the package insert.

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.

We note that your August 13, 2013, submission includes final printed labeling (FPL) for your package inserts. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

**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 package insert, 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 includes 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 MS Word format, that includes the changes approved in these supplemental applicationa, 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 Carmen DeBellas, Regulatory Project Manager, at (301) 796-1203.

Sincerely,

*{See appended electronic signature page}*

Sumathi Nambiar, MD, MPH
Acting Director
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/

---

SUMATHI NAMBIAR
09/09/2013