DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-739/S-017
NDA 50-749/S-023

SUPPLEMENT APPROVALS

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

Dear Mr. Baker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated July 31, 2015, received, July 31, 2015, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- NDA 50-739: Omnicef (cefdinir) Capsules, 300 mg
- NDA 50-749: Omnicef (cefdinir) Oral Suspension, 125 mg/5mL and 250 mg/5mL

These Prior Approval supplemental applications, submitted in response to the Agency's supplement request letter dated June 11, 2015, provide for revisions to the **CLINICAL PHARMACOLOGY** section, **Microbiology** subsection and the **REFERENCES s**ection of package insert, as well as minor editorial revisions, so as to furnish adequate information for the safe and effective use of these drugs.

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 and with the minor editorial revision listed below and indicated in the enclosed labeling:

- The text, "Susceptibility of staphylococci to cefdinir may be deduced from testing penicillin and either cefoxitin or oxacillin. Staphylococci susceptible to oxacillin (cefoxitin) can be considered susceptible to cefdinir.[3]" is to be indented and included immediately after the last footnote to Table 1: Susceptibility Test Interpretive Criteria for Cefdinir, rather than being presented in paragraph 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, 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 these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submissions, provide a highlighted or marked-up copy that shows all changes, as well as clean Microsoft Word versions. The marked-up copies 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 approved NDAs (21 CFR 314.80 and 314.81).

If you have any questions, call J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, MD, MPH
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
11/18/2015