DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21606/S-012, S-014

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: David Desris, Pharm.D.
Director, US & Canada Regulatory Affairs
Department PA77/Building AP30
1 N. Waukegan Road
North Chicago, IL 60064

Dear Dr. Desris:

Please refer to your Supplemental New Drug Applications (sNDAs) dated February 10, 2012, (S-012) and October 21, 2013 (S-014), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zemplar (paricalcitol) capsules.

We acknowledge receipt of your amendments dated January 13, and May 6, 2013, submitted to supplement -012.

These "Prior Approval" supplemental new drug applications provide for the following revisions to the package insert:

-Supplement -012 provides for revisions to the WARNINGS AND PRECAUTIONS section, Laboratory Tests subsection (5.3) to state "In pre-dialysis patients, Zemplar Capsules may increase serum creatinine and therefore decrease the estimated GFR (eGFR). Similar effects have also been seen with calcitriol." In addition, the ADVERSE REACTIONS section, Postmarketing Experience subsection (6.2) has been revised to include blood creatinine increase.

-Supplement -014 provides for revisions to the ADVERSE REACTIONS section, Postmarketing Experience subsection (6.2) to add "hypercalcemia" and to state that the reactions have been reported during postapproval use and postapproval clinical trials. In addition, system organ classifications for the adverse reactions have been added.

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 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 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 Meghna Jairath, Regulatory Project Manager, at (301) 796-4267.

Sincerely,

{See appended electronic signature page}

Jean-Marc Guettier, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
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/

JENNIFER R PIPPINS
08/29/2014
Signing for Dr. Guettier