DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020528/S-021

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Viraj B. Gandhi
Manager, Regulatory Affairs - PPG
1 N Waukegan Road
Dept. PA77/Bldg. AP30
North Chicago, IL 60064

Dear Mr. Gandhi:

Please refer to your Supplemental New Drug Application (sNDA) dated August 7, 2012, received August 7, 2012, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Mavik (trandolapril) 1 mg, 2 mg and 4 mg Tablets.

This "Prior Approval" supplemental new drug application provides for revision to the labeling as follows:

1. Under **PRECAUTIONS, Drug Interactions,** the following text was added:

   Dual Blockade of the Renin-Angiotensin System (RAS)
   Dual blockade of the RAS with angiotensin receptor blockers, ACE inhibitors, or aliskiren is associated with increased risks of hypotension, hyperkalemia, and changes in renal function (including acute renal failure) compared to monotherapy. Closely monitor blood pressure, renal function and electrolytes in patients on MAVIK and other agents that affect the RAS.

   Do not co-administer aliskiren with MAVIK in patients with diabetes. Avoid use of aliskiren with MAVIK in patients with renal impairment (GFR <60 ml/min).

2. Under **CONTRAINDICATIONS**, the following text was added:

   Do not co-administer aliskiren with MAVIK in patients with diabetes (see **PRECAUTIONS, Drug Interactions**).

3. The revision date and revision number were updated.

There are no other changes from the last approved package insert.

We have completed our review of this supplemental application, and it is 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 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, please contact Lori Anne Wachter, RN, BSN, Regulatory Project Manager for Safety at (301) 796-3975.

Sincerely,

{See appended electronic signature

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

MARY R SOUTHWORTH
09/11/2012