DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22417/S-8
NDA 20659/S-57

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: Nancy Aiello
Associate Director, RA PPG
1 N. Waukegan Road
Dept. PA77/Bldg. AP30-1
North Chicago, IL 60064

Dear Ms. Aiello:

Please refer to your Supplemental New Drug Applications (sNDAs) dated May 25, 2012, received May 25, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norvir® (ritonavir) 100 mg tablet and Norvir® (ritonavir) 80 mg/mL oral solution.

We acknowledge receipt of your amendments dated June 18, 2012, October 1, 2012, October 19, 2012, and November 15, 2012.

These Prior Approval supplemental new drug applications propose the following changes:

1. To add information regarding potential toxicities associated with the use of Norvir oral solution in preterm neonates to DOSAGE AND ADMINISTRATION, WARNINGS AND PRECAUTIONS, Toxicity in Preterm Neonates, and the OVERDOSE, Management of Overdosage, sections of the package insert.

2. To add drug interaction information regarding avanafil, budesonide, raltegravir and rivaroxaban to the package insert.

3. To add ritonavir exposure information from the 2011 Antiretroviral Pregnancy Registry to section 8, USE IN SPECIFIC POPULATIONS, Pregnancy section of the package insert.

4. To add avanafil information to the PATIENT COUNSELING INFORMATION section of the package insert.

5. To add rivaroxaban, budesonide and avanafil information to the patient package insert section titled, “What should I tell my doctor before taking NORVIR?”

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 and patient 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, call Mammah Sia Borbor, M.S., M.B.A., Regulatory Project Manager, at (301) 796-7731 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Kendall Marcus, M.D.
Associate Director of Safety
Division of Antiviral Products
Office of Antimicrobial Products
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/

JEFFREY S MURRAY
11/20/2012