



NDA 21906/S-38
NDA 21251/S-45

SUPPLEMENT APPROVAL

AbbVie, Inc.
Attention: Matthew Kuntz, PharmD, MBA, RAC
Director, Regulatory Area & Affiliate Strategy, US & Canada
1 N. Waukeagan Road
Dept. PA77/Bldg. AP30-1
North Chicago, IL 60064

Dear Dr. Kuntz:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received July 17, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for KALETRA[®] (lopinavir/ritonavir) 80/20 mg/mL oral solution and 100/25mg and 200/50mg tablets.

We acknowledge receipt of your amendments dated November 30, 2012, and December 12, 2012.

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

1. To align labeling for the oral solution and tablet formulations with the editorial changes approved under NDA 21226/S-36, Kaletra soft gelatin capsules
2. To include previously approved patient populations in the INDICATIONS AND USAGE section
3. To add drug-drug interaction information to package insert and the MEDICATION GUIDE with information pertaining to the co-administration of Kaletra with avanafil, boceprevir, budesonide, lamotrigine, raltegravir, rivaroxaban, telaprevir, and valproate.
4. To reorder WARNINGS AND PRECAUTIONS by listing them in decreasing order of importance.

We have completed our review of these supplemental applications, as amended. 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, text for the patient package insert, Medication Guide), 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Linda C. Onaga, Regulatory Project Manager, at (301) 796-0759 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Kendall Marcus, MD
Deputy Director for 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/

KENDALL A MARCUS
01/17/2013