



NDA 21-906/S-017

NDA 21-251/S-026

Abbott Laboratories  
Attention: Mary Konkowski  
Manager, Global Pharmaceutical Regulatory Affairs  
Dept. PA76/Building AP30-1NE  
200 Abbott Park Road  
Abbott Park, IL 60064-6157

Dear Ms. Konkowski:

Please refer to your supplemental new drug applications dated June 25, 2008, received June 25, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA<sup>®</sup> (lopinavir/ritonavir) Tablets 200 mg/50 mg, 100 mg/25 mg and KALETRA<sup>®</sup> (lopinavir/ritonavir) Oral Solution 80 mg/20mg per ml.

We acknowledge receipt of your submissions dated June 25, 2008, August 06, 2008, September 24, 2008, October 17, 2008, October 24, 2008, January 02, 2009, February 19, 2009, March 27, 2009 and April 10, 2009.

These supplemental new drug applications proposed the following changes:

- To Update the Dosage and Administration (2.1), Adverse Reactions (6.1), Clinical Studies (14), and Information For Patients (17.1) sections of the package insert based on the 48-week results for Study M05-730 entitled, "A Phase 3, Randomized, Open-label study of Lopinavir/ritonavir Tablets Versus Soft Gel Capsules and Once Daily Versus Twice Daily Administration, when Coadministered with NRTIs in Antiretroviral Naïve HIV-1 Infected Subjects".

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (text for the package insert).

Approval of this supplement fulfills postmarketing commitment number 1 written in the October 25, 2008 approval letter. The commitment is listed below:

1. Submit the final clinical study report for M05-730 entitled "A Phase 3, Randomized, Open label study of lopinavir/ritonavir Tablets Versus Soft Gel Capsules and Once Daily Versus Twice Daily Administration, when Coadministered with NRTIs in Antiretroviral Naïve HIV-1 Infected Subjects".

## **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert, text for the Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, “**SPL for approved NDA 21-906/S-017 and NDA 21-251/S-026.**”

In addition, within 21 days of the date of this letter, amend any pending applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in these applications.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the medication guide).

## **PROMOTIONAL MATERIALS**

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/the Division of Antiviral Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

## **LETTERS TO HEALTHCARE PROFESSIONALS**

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Rashmi Kalla, PharmD, Regulatory Project Manager, at (301) 796-3931.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.  
Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

Enclosure: Draft Package Insert  
Draft Medication Guide

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Jeffrey Murray  
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