



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-226/S-018

Abbott Laboratories
Attention: Raymond C. Votzmeyer
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Road
Dept. RA76/Building AP30-1NE
Abbott Park, IL 60064-6157

Dear Mr. Votzmeyer:

Please refer to your supplemental new drug application dated June 19, 2006, received June 20, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA[®], (133.3 mg Lopinavir/33.3 mg Ritonavir) Capsules.

We acknowledge receipt of your submissions dated February 6, 2007 and April 2, 2007.

This supplemental new drug application provides for the use of KALETRA[®] (Lopinavir/Ritonavir) capsules in combination with other antiretroviral agents for the treatment of HIV infection.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text. The approval was based on review of one phase 2 trial (M97-720) used to support long-term (Week 360) efficacy and safety data.

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-226/S-018.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and

effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for neonates to < 6 months and adolescents from 12 years to 16 years until June 30, 2007.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Multiple-dose pharmacokinetics, safety and activity study of ABT-378/ritonavir in combination with other antiretroviral agents in HIV-infected pediatric patients

Submission date: June 30, 2007

2. Multiple-dose pharmacokinetic and safety study of ABT-378/ritonavir in HIV-exposed neonates (born to HIV-infected mothers).

Submission date: June 30, 2007

We also remind you of additional post-marketing commitments outlined in the January 18, 2002 and October 28, 2005 approval letters.

Submit final study reports to the NDA. For administrative purposes, all submissions related to pediatric postmarketing study commitments must be clearly designated “**Required Pediatric Study Commitments**”.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Karen Winestock, Regulatory Project Manager, at (301) 796-0834.

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

Enclosures: Package Insert and Patient Package Insert

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Jeffrey Murray
4/20/2007 10:52:20 AM
For D. Birnkrant