



NDA 21-251/S-022

NDA 21-906/S-013

Abbott Laboratories
Attention: Mary Konkowski
Manager, Global Pharmaceutical Regulatory Affairs
Dept. PA 76, Building AP30-1E
200 Abbott Park Road,
Abbott Park, IL 60064-6157

Dear Ms. Konkowski:

Please refer to your supplemental new drug applications dated December 21, 2007 received December 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA[®] (lopinavir/ritonavir) Oral Solution and KALETRA[®] (lopinavir/ritonavir) Tablets .

We acknowledge receipt of your submissions dated January 22, 2008, January 30, 2008, March 28, 2008, May 20, 2008, June 12, 2008, June 17, 2008 and January 18, 2008.

These supplemental new drug applications provide for the use of KALETRA[®] (lopinavir/ritonavir) Oral Solution for the treatment of HIV-1 infection in pediatric patients 14 days to 6 months of age and from 12 to 18 years of age. In addition, the patient package insert sections entitled, "What is Kaletra and how does it work?" and How Should I Take Kaletra?" were updated with information regarding pediatric patients age 14 days and older.

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 and with the minor editorial revision listed below and included in the enclosed package insert. This revision is the term of the approval of these applications.

- The following footnote was added to the DOSAGE AND ADMINISTRATION section's Table 2:

†Please refer to the individual product labels for appropriate dosing in children.

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

Within 21 days of the date of this letter, submit 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

NDA 21-251/S-022

NDA 21-906/S-013

Page 2

identical in content to the enclosed labeling text (package insert and patient package insert). Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We note that you have fulfilled the pediatric study requirement for all relevant pediatric age groups for NDA 21-251.

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 the Division of Division of Antiviral Products and two copies of both the promotional materials and the package inserts 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

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

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

NDA 21-251/S-022

NDA 21-906/S-013

Page 3

If you have any questions, call Karen Winestock, Chief, Project Management Staff, 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

Enclosure (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
6/20/2008 04:41:31 PM