

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-906

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-906

Abbott Laboratories
Attention: Mary Ellen Snyder
Associate Director, Global Pharmaceutical Regulatory Affairs
200 Abbott Park Rd
Dept 491, Bldg. AP30-1NE
Abbott Park, Illinois 60064-6157

Dear Ms Snyder:

Please refer to your new drug application (NDA) dated April 28, 2005, received April 29, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA (lopinavir/ritonavir) tablets (200mg/50mg).

We completed our review of this application, as amended. It is approved, effective on the date of this letter. This new drug application provides for the use of KALETRA tablets in combination with other antiretroviral agents for the treatment of HIV-infection.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 21-906.**" 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 waiving the pediatric study requirement for this application.

We remind you of your postmarketing study commitment agreed upon during the October 21, 2005 teleconference. This 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".

Final Report Submission: on or by June 30, 2008

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled **"Postmarketing Study Commitment Protocol", "Postmarketing Study Commitment Final Report", or "Postmarketing Study Commitment Correspondence."**

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

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

In addition, please submit one market package of the drug product when it is available.

If you have any questions, call Vasavi Reddy, RPh, MPH, Regulatory Project Manager at (301) 796-0793.

Sincerely,

{See appended electronic signature page}

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

Enclosure: FPL (to be attached)