DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-226/S-012
NDA 21-251/S-009

Abbott Laboratories
Attention: Greg Bosco
Associate Director, PPD Regulatory Affairs
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Dear Mr. Bosco:

Please refer to your supplemental new drug applications dated June 2, 2003, received June 3, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA ® (lopinavir/ritonavir) Capsules and KALETRA ® (lopinavir/ritonavir) Oral Solution.

We acknowledge receipt of your amended submissions dated July 23, 2003, October 3, 2003, October 23, 2003, December 2, 2003, and December 3, 2003.

These supplemental new drug applications provide updates to the CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS: Drug Interactions and DOSAGE AND ADMINISTRATION sections of the package insert and other minor labeling revisions throughout the package insert and patient package insert.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert) and contain any agreed upon modifications.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-226/S-012" and "FPL for approved supplement NDA 21-251/S-009." Approval of these submissions by FDA is not required before the labeling is used.

.

We also remind you of your outstanding post-marketing study commitments outlined in the original

accelerated approval letter dated September 15, 2000.

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to these NDAs. 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 these NDAs. 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 Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."**

(b)(4)----------
-

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Sean J. Belouin, R.Ph, Regulatory Project Manager, at 301-827-2335.

Sincerely,

{See appended electronic signature page}

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

Enclosure

(Nos. 3956 and 3959)
NEW

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

/s/

Debra Birnkrant
12/3/03 05:39:19 PM
NDA 21-226, 21-251