DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-226/S-017
NDA 21-251/S-011

Abbott Laboratories
ATTN: Mary Ellen Snyder
200 Abbott Park Road
D-491, AP30-1E
Abbott Park IL 60064-6157

Dear Ms Snyder:

Please refer to your supplemental new drug applications dated October 13, 2004, received October 13, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA (lopinavir/ritonavir) capsules and oral solution.

These supplemental new drug applications provide for changes in labeling incorporating fluticasone and trazodone interaction information under the Drug Interactions subsection of the WARNINGS section and Table 9 under Drug Interactions subsection of the PRECAUTIONS section.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling for the package insert submitted February 24, 2005.

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, HFD-410
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, please call Vasavi Reddy, RPh, Regulatory Project Manager, at (301) 827-2413.

Sincerely,

{See appended electronic signature page}

Jeffrey Murray, M.D., M.P.H.
Deputy Director
Division of Antiviral Drug Products
Office Drug Evaluation IV
Food and Drug Administration

Attachment:
FDL

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
3/28/05 10:04:11 AM