DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-251/S-017

Abbott Laboratories
Attention: Nancy P. Aiello
Regulatory Affairs Manager
Global Pharmaceutical Regulatory Affairs
Dept. PA71/Building AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Aiello:

Please refer to your supplemental new drug application dated March 13, 2007, received March 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for KALETRA® (lopinavir/ritonavir), Oral Solution.

We acknowledge receipt of your submission dated July 23, 2008.

This supplemental new drug application provides for revisions to the carton and container labels.

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 final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels).

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 21-251/S-017**." Approval of this submission by FDA is not required before the labeling is used.

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).

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 (Carton and Container labels)

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

7/30/2008 03:47:41 PM