DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-659/S-036
NDA 20-945/S-018

Abbott Laboratories, Inc.
Attention: Mary Konkowski
Manager Global Pharmaceutical Regulatory Affairs
Dept. RA76/Building AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064/6157

Dear Ms. Konkowski:

Please refer to your supplemental new drug applications dated November 14, 2006, received November 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR® (100 mg ritonavir capsules) Soft Gelatin and NORVIR® (80 mg/mL ritonavir oral solution).

We acknowledge receipt of your submissions dated February 2, 2007.

These supplemental new drug applications provide for revisions to the CLINICAL PHARMACOLOGY, Drug-Drug Interactions, WARNINGS, Drug Interactions, PRECAUTIONS, Drug Interactions, and DOSAGE and ADMINISTRATION sections to include the following:

- Removal of saquinavir 400 mg twice daily in combination with ritonavir 400 mg or 600 mg twice daily co-administration information from the CLINICAL PHARMACOLOGY, Drug-Drug Interaction and DOSAGE AND ADMINISTRATION sections of the package insert.

- Revising the WARNINGS section, to include language related to the risk of patients acquiring clinical hepatitis and hepatic decompensation when tipranavir is co-administered with ritonavir.

- The addition of prescribing information related to atazanavir, darunavir, fosamprenavir and saquinavir when co-administered with ritonavir to PRECAUTIONS, Drug Interaction's Table 6 entitled, "Established and Other Potentially Significant Drug Interactions: Alteration in Dose or Regimen Recommended Based on Drug Interaction Studies or Predicted Interaction".

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.

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

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 these submissions "**FPL for approved supplement NDA 20-659/S-036 and NDA 20-945/S-018**." Approval of these submissions 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 these NDAs and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, Regulatory Project Manager, 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

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

5/10/2007 09:11:42 PM