DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-659/S-043
NDA 20-945/S-023

Abbott Laboratories
Attention: Mary S. Konkowski
Manager, Global Pharmaceutical Regulatory Affairs
Dept. PA76 / BLDG. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Konkowski

Please refer to your supplemental new drug applications dated March 31, 2008, received March 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR®, (ritonavir) 80 mg/ml Oral Solution and 100 mg Capsules.

We acknowledge receipt of your submissions dated May 15, 2008, and September 19, 2008. Reference is also made to your electronic mail correspondence dated September 29, 2008.

These supplemental new drug applications provide for the revision of the **Dosage and Administration** section of the U.S. package insert to include a new dose modification subsection and updates Table 6 in **Precautions – Drug Interactions** with information on drug interactions between ritonavir and bupropion, maraviroc, vincristine and vinblastine.

We have 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 and with the minor editorial revisions agreed to on September 29, 2008 as listed below:

Anticancer Agents: vincristine, vinblastine	↑anticancer agents	Concentrations of vincristine or vinblastine may be increased when co-administered with ritonavir resulting in the potential for increased adverse events usually associated with these anticancer agents Consideration should be given to temporarily withholding the ritonavir containing antiretroviral regimen in patients who develop significant hematologic or gastrointestinal side effects when ritonavir is administered concurrently with vincristine or vinblastine. Clinicians should be aware that if the ritonavir containing regimen is withheld for a prolonged period, consideration should be given to altering the regimen to not include a CYP3A or P-gp inhibitor in order to control HIV-1 viral load.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions listed, the enclosed labeling (text for the package insert and text for the patient package insert,) and/or submitted labeling (package insert and patient package insert submitted September 19, 2008). These revisions are terms of the NDA supplement approval. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission **"SPL for approved supplements NDA 20-659/S-043 and NDA 20-945/S-023."**

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 Kwadwo (Kojo) Awuah, Pharm.D, Regulatory Project Manager, at (301) 796-0608.

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

Enclosures: Package Insert (PI)
Patient Package Insert (PPI)

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

/s/

Kendall Marcus

10/1/2008 07:37:31 AM