DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-659/S-030
NDA 20-945/S-013

Abbott Laboratories
Attention: Greg Bosco
Associate Director, PPD, Regulatory Affairs
200 Abbott Park Road
D-491, AP30-1E
Abbott Park, IL 60064-6157

Dear Mr. Bosco:

Please refer to your supplemental new drug applications dated January 13, 2003 and received January 14, 2003, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Norvir™ (ritonavir) 100 mg Capsules and 80 mg/mL Oral Solution. We also acknowledge receipt of your amended submissions dated February 7, 2003, February 12, 2003, May 9, 2003, June 19, 2003, and July 10, 2003.

These supplemental new drug applications contain labeling revisions to the **Drug-Drug Interactions** subsection and a modified **Hepatic Insufficiency** statement in the **CLINICAL PHARMACOLOGY** section, revisions to the **CONTRAINDICATIONS** and **WARNINGS** sections, revisions to the **Drug Interactions** subsection of the **PRECAUTIONS** section, revisions to the **Post Marketing** subsection of the **ADVERSE REACTIONS** section, and revisions to the **Dose Adjustment in Hepatic Insufficiency** subsection of the **DOSAGE AND ADMINISTRATION** section of the package insert. Additional minor labeling revisions were incorporated in the 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 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 amended submitted draft labeling (dated July 10, 2003).

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 20-659/S-030, 20-945/S-013." Approval of these submissions by FDA is not required before the labeling is used.

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 these NDA's 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

Attachment

---

**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
9/10/03 02:00:42 PM