NDA 20-659/S-026
NDA 20-945/S-007

Abbott Laboratories
Attention: Rebecca A. Welch
PPD, Regulatory Affairs
D-491/AP6B-1SW
100 Abbott Park Road
Abbott Park, IL 60064-6108

6 MAR 2001

Dear Ms. Welch:

Please refer to your supplemental new drug applications dated January 23, 2001, received January 24, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvir® (ritonavir) 100mg capsules and 80mg/mL oral solution.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the following statement to the bottle and container labels (Alert Box) and in the package insert and patient package insert: “ALERT: Find out about medicines that should NOT be taken with NORVIR”

We have completed the review of these supplemental applications, 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 submitted final printed labeling (package insert submitted January 23, 2001, patient package insert submitted January 23, 2001, immediate container and carton labels submitted January 23, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

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 this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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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,

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research