DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-659/S-027
NDA 20-945/S-008

Abbott Laboratories
Attention: Rebecca A. Welch
Director, PPD Regulatory Affairs
D-491/AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Welch:

Please refer to your supplemental new drug applications dated November 20, 2001, received November 21, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR™ (ritonavir) 100mg soft gelatin capsules and NORVIR™ (ritonavir) 80mg/ml oral solution.

We acknowledge receipt of your submission dated November 20, 2001.

These "Changes Being Effected" supplemental new drug applications provide for label revisions regarding fat redistribution in the package and patient package inserts.

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 November 20, 2001, patient package insert submitted November 20, 2001). Accordingly, these supplemental applications are approved effective on the date of this letter.

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 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/

Debra Birnkrant
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NDA 20-659, 20-945