DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-945/S-026
NDA 20-659/S-047

SUPPLEMENT APPROVAL

Abbott Laboratories
Attention: Mary 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 May 29, 2009, received May 29, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

Norvir® (ritonavir) Capsule
Norvir® (ritonavir) Solution

Reference is also made to the FDA correspondence dated October 14, 2009 and November 12, 2009 and to your amendments dated November 3, 2009 and November 18, 2009.

These Prior Approval supplemental new drug applications provides for:

- ***Updates to the U.S package insert to include drug-drug interaction information for concurrent ritonavir administration with inhaled medicines such as salmeterol or salmeterol in combination with fluticasone propionate (Serevent®, Advair®).***

- ***Updates to the U.S package insert to include drug-drug interaction information for concurrent ritonavir administration with sildenafil (Revatio®).***

- ***Updates to the U.S. package insert to include revisions to the Contraindications section, the Warnings section and the Precautions: Drug Interactions section.***

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 enclosed, agreed-upon labeling text.

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)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to

the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide). For administrative purposes, please designate this submission, "SPL for approved **N20-945/S026 and N20-659/S047".**

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
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 Paras M. Patel, Regulatory Project Manager, at (301) 796-0783.

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:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20659	SUPPL-47	ABBOTT LABORATORIES PHARMACEUTICAL PRODUCTS DIV	NORVIR (RITONAVIR) ORAL SOLUTION
NDA-20945	SUPPL-26	ABBOTT LABORATORIES	NORVIR(RITONAVIR)SEC CAPS 100/200MG

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

/s/

PARAS M PATEL
11/23/2009

KENDALL A MARCUS
11/23/2009