DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-659/S-45 **SUPPLEMENT APPROVAL**

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

Dear Ms. Konkowski:

Please refer to your supplemental new drug application dated December 19, 2008, received December 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for NORVIR® (ritonavir) oral solution.

We also acknowledge receipt of your submissions dated February 5, 2009, September 11, 2009, September 15, 2009, September 24, 2009, September 29, 2009, October 1, 2009, October 5, 2009, October 7, 2009, and October 13, 2009, December 11, 2009, January 13, 2010, January 18, 2010, and January 22, 2010.

This "Prior Approval" supplemental new drug application updates the package insert and patient package insert with information regarding the new Norvir Tablet formulation. Norvir Oral Solution will share the same labeling with Norvir Tablet when the tablet formulation is approved.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

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 and patient package insert). For administrative purposes, please designate this submission, "SPL for approved NDA 20-659/S-45.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

LETTERS TO HEALTH CARE PROFESSIONALS

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

REPORTING REQUIREMENTS

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 Amalia Himaya, Regulatory Project Manager, at (301) 796-3391 or (301) 796-1500.

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 and Patient Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20659	SUPPL-45	ABBOTT LABORATORIES PHARMACEUTICAL PRODUCTS DIV	NORVIR (RITONAVIR) ORAL SOLUTION

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

/s/

DEBRA B BIRNKRANT
02/10/2010