DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-417 **NDA 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 new drug application (NDA) dated December 19, 2008, received December 19, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR® (ritonavir) 100mg tablets.

We also acknowledge receipt of your submissions dated January 23, 2009, January 28, 2009, January 29, 2009, February 5, 2009, February 9, 2009, February 13, 2009, March 10, 2009, March 31, 2009, April 27, 2009, May 14, 2009, June 3, 2009, July 17, 2009, July 24, 2009, August 4, 2009, August 5, 2009, September 4, 2009, September 11, 2009, September 15, 2009, September 22, 2009, September 24, 2009, September 29, 2009, October 1, 2009, October 5, 2009, October 7, 2009, October 13, 2009, December 11, 2009, January 13, 2010, January 18, 2010, and January 22, 2010.

The December 11, 2009, submission constituted a complete response to our October 16, 2009, action letter.

This new drug application provides for the use of a 100 mg NORVIR® (ritonavir) Tablet for the treatment of HIV-1 infection. Information related to the ritonavir tablet for the PEPFAR program was also included in this submission.

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.

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.

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)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, 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 22-417**."

IMMEDIATE CONTAINER LABEL

Submit final printed container label that is identical to the enclosed immediate container label as soon as this is available, but no more than 30 days after this is printed. Please submit the label electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Container Label for approved NDA 22-417**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages birth to less than 1 month of age because studies are impossible or highly impracticable. This is because there are too few children with the disease or condition and those with the disease or condition are geographically dispersed.

This product is appropriately labeled for use in ages 1 month to 16 years for this indication. Therefore, no additional pediatric studies are needed in this pediatric group.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA

2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.
Please submit one market package of the drug product when it is available.

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
Suite 12B-05
5600 Fishers Lane
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, Patient Package Insert, and Container Label

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22417	ORIG-1	ABBOTT LABORATORIES	Ritonavir Tablet

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