DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20659/S-55
NDA 22417/S-06

**SUPPLEMENT APPROVAL**

Abbott Laboratories
Attention: Nancy Aiello
Manager, Regulatory Affairs – PPG
Dept. 77, Bldg, Ap30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Aiello:

Please refer to your Supplemental New Drug Application (sNDA) dated June 6, 2011, received June 7, 2011 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norvir® (ritonavir) tablets, 100 mg and oral solution, 80 mg/mL.

We acknowledge receipt of your amendments dated June 29, 2011, November 21, 2011 and December 2, 2011.

This Prior Approval supplemental new drug application proposes the following changes:

1. To update the WARNINGS, Drug Interaction (5.1) subsection to include information related to coadministration of ritonavir with medications that metabolized CYP3A inhibitors.

2. To update the Adverse Reactions (6) section and the Drug Interactions, Table 5 (7.2) subsection of the package insert with new information on toxic epidermal necrolyis (TEN) and drug interactions with fentanyl, dasatinib and nilotinib, respectively.

3. To update the What should I tell my doctor before taking NORVIR? section of the patient package insert with new information on the drug interaction information with fentanyl, dasatinib and nilotinib.

We have completed our review of this supplemental 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

## PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form

FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

**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 Linda C. Onaga, MPH Regulatory Project Manager, at (301) 796-0759.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

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/s/

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KENDALL A MARCUS
12/06/2011