



NDA 020945/S-028

**SUPPLEMENT APPROVAL**

Abbott Laboratories  
Attention: Mary Konkowski  
Associate Director, 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 and received February 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Norvir® (ritonavir) capsules.

We also acknowledge receipt of your submissions dated March 10, 2010 and March 26, 2010.

Reference is also made to our letter dated January 13, 2010, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for NORVIR (ritonavir) capsules. This information pertains to the risk of drug-drug interactions with the use of protease inhibitors, including NORVIR (ritonavir).

This supplemental application provides for revisions to the labeling regarding coadministration of certain drugs with NORVIR (ritonavir) capsules.

The following changes are consistent with our January 13, 2010 Safety Labeling Change Notification letter: the PRECAUTIONS-Drug Interactions section of the labeling has been updated with the following information:

- The addition of new dosing recommendations for bosentan and tadalafil when prescribed for the treatment of pulmonary arterial hypertension.
- The addition of new dosing recommendations for colchicine when prescribed for the treatment of familial Mediterranean fever or gout.

Agreed-upon changes are as follow:

- The addition of new dosing recommendations for colchicine when prescribed for the prophylaxis of gout.
- The addition of the recommendation that colchicine should not be coadministered with NORVIR (ritonavir) in patients with hepatic or renal impairment.

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

### **CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), 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 and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements. 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 pending “Changes Being Effected” (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.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

### **PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

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

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. 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>.

### **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, please contact Amalia Himaya, Regulatory Project Manager, at (301) 796-3391 or the Division’s main number at (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

Enclosure  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20945	SUPPL-28	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/

KENDALL A MARCUS  
04/27/2010