



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-945/S-019

Abbott Laboratories  
Attention: Nancy P. Aiello  
Regulatory Affairs Manager  
Global Pharmaceutical Regulatory Affairs  
Dept. PA71/Bldg AP30-1E  
200 Abbott Park Road  
Abbott Park, IL 60064-6157

Dear Ms. Aiello:

Please refer to your supplemental new drug application dated March 13, 2007, received March 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR<sup>®</sup>, (ritonavir) 100 mg Soft Gelatin Capsules.

This supplemental new drug application provides for revisions to the immediate container and carton labels.

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-945/S-019.**" Approval of this submission by FDA is not required before the labeling is used.

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

MedWatch  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

NDA 20-945/S-019

Page 2

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 Karen Winestock, Chief, Project Management Staff, at (301) 796-0834.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure (immediate container and carton labels)

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Jeffrey Murray  
5/16/2008 04:11:05 PM