



NDA 20-945/S-016

NDA 20-659/S-033

Abbott Laboratories  
ATTN: Mary Ellen Snyder  
Global Pharmaceutical Regulatory Affairs  
Dept RA76, AP30-1E  
200 Abbott Park Road  
Abbott Park, IL 60064-6157

Dear Ms Snyder:

Please refer to your supplemental new drug applications dated , February 11, 2005 received February 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NOVIR (ritonavir) capsules and oral solution.

Your submission received September 23, 2005 constituted a complete response to our approvable letter dated August 12, 2005.

These supplemental new drug applications provide for updates to CLINICAL PHARMACOLOGY, WARNING, PRECAUTIONS, and PATIENT INFORMATION sections of the package insert. The following information was included:

- Addition of pharmacokinetic and/or safety data for tadalafil, vardenafil, voriconazole and the contraceptive patch.
- Addition of pharmacokinetic and/or safety data for buspirone, digoxin, and delavirdine based on literature and post-marketing reports.
- Addition of Immune reconstitution syndrome text as requested by the Division on February 8, 2005.
- Addition of  $C_{min}$  data to the drug interaction Tables 2 and 3 in the Clinical Pharmacology section.
- Revised drug interaction tables in the PRECAUTION section.
- Addition of clinical comment for alfuzozin regarding the rationale for the contraindication.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 these submission "**FPL for approved supplement NDA 20-945/S-016 and NDA 20-659/ S-033.**"

Approval of these submissions by FDA is not required before the labeling is used.

NDA 20-945/S-016

NDA 20-659/S-033

Page 2

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, HFD-410  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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 Vasavi Reddy, RPh, MPH, Regulatory Project Manager, at (301) 796-0793.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.  
Division Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation  
Food and Drug Administration

Enclosure (label)

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/s/

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Jeffrey Murray  
11/9/2005 02:02:02 PM