



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-659/S-034  
NDA 20-945/S-017

Abbott Laboratories  
Attn: Mary Ellen Snyder  
Associate Director, Global Pharmaceutical Regulatory Affairs  
200 Abbott Park Road  
Dept RA76, Bldg, APO30-1NE  
Abbott Park, IL 60064-6157

Dear Ms Snyder:

Please refer to your supplemental new drug application 20-659 (034) and 20-945 (017) dated April 6, 2005 received on April 7, 2005 submitted under section 505(b) (1) of the Federal Food, Drug, and Cosmetic Act for NORVIR (ritonavir) oral solution and soft gelatin capsules.

These supplemental new drug applications provide for the use of NORVIR (ritonavir) oral solution in combination with other antiretroviral agents for the treatment of HIV-infection in pediatric patients from one month to two years of age.

We completed our review of these applications. These applications are 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 text for the package insert and text for the patient package insert.

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 20-659/S-034 & 20-945/S-017**". Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to

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the Division of Antiviral Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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, Regulatory Project Manager, at (301) 796-0793.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.  
Director  
Division of Antiviral Products  
Center for Drug Evaluation & Research  
Food & Drug Administration

Enclosure (label)

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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  
10/6/2005 09:28:09 AM