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Approval Package

APPLICATION NUMBER:

20-659/S-13
20-680/S-11

Trade Name: Norvir®

Generic Name: (ritonavir capsules)
(ritonavir oral solution)

Sponsor: Abbott Laboratories

Approval Date: May 26, 1999

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APPLICATION NUMBER:

20-659/S-13
20-680/S-11

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Pharmacology Review(s)	
Statistical Review(s)	**X**
Microbiology Review(s)	
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Administrative and Correspondence Document(s)	**X**

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APPLICATION NUMBER:

20-659/S-13
20-680/S-11

APPROVAL LETTER

MAY 26 1999

NDA 20-659/S-013
NDA 20-680/S-011

Abbott Laboratories
Pharmaceutical Product Division
Attention: Rebecca A. Welch
Associate Director, Regulatory Affairs
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

Dear Ms. Welch:

Please refer to your supplemental new drug applications dated May 22, 1998, received May 26, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVIR (ritonavir oral solution) 80 mg/mL and NORVIR (ritonavir capsules) 100 mg.

We acknowledge receipt of your submissions dated July 28, 1998, and April 16, May 5, 14, 18, and 25, 1999.

These supplemental applications provide information to fulfill the accelerated approval commitments as required under 21 CFR 314.510. Specifically, these new drug applications provide for the use of NORVIR, in combination with other antiretroviral agents, for the treatment of HIV-infection.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the draft labeling submitted on May 25, 1999. Accordingly, these supplemental applications are approved effective on the date of this letter. Approval of these supplements fulfills your commitments made under 21 CFR 314.510.

In addition, these applications provide for the changes in the CLINICAL PHARMACOLOGY, INDICATIONS AND USAGE, Description of Clinical Studies, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION sections of the package insert.

These revisions are terms of the approval.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-659/013, 20-680/011." In addition, please submit an electronic copy of the label in MS Word. Approval of these submissions by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you of your Phase 4 commitments specified in your submission dated May 18, 1999. These commitments include:

1. [redacted]
2.
3.
4.

We also remind you of the Phase 4 commitments specified in your letter dated February 27, 1996.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report.

For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632). We note that at this time you have not fulfilled all the requirements of 21 CFR 314.55. We are deferring submission of reports of additional pediatric studies in patients less than two years of age, including neonates, until July 1, 2001. Additionally, please refer to our Pediatric Written Request letter dated April 16, 1999.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity).

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Sylvia D. Lynche, Pharm.D., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

Heidi Jolson

Heidi M. Jolson, M.D., M.P.H.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research