CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: NDA 20828

Trade Name: FORTOVASE

Generic Name: SAQUINAVIR

Sponsor: HOFFMAN-LAROCHE

Approval Date: NOVEMBER 7, 1997

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APPLICATION: NDA 20828

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	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
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Final Printed Labeling		X		
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI	X			
Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)	X			
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Correspondence				

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APPLICATION NUMBER: NDA 20828

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 7 1997

NDA 20-828

Robin L. Conrad, Program Manager
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110

Dear Ms. Conrad:

Please refer to your new drug application dated May 9, 1997, received May 12, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for FORTOVASE (Saquinavir Soft Gelatin Capsule) 200 mg.

We acknowledge receipt of your submissions dated:

May 15, 1997	July 9, 1997	August 21, 1977	October 15, 1997
May 19, 1997	July 10, 1997	August 25, 1997	October 16, 1997
May 20, 1997	July 11, 1997	August 26, 1997	October 17, 1997
May 30, 1997	July 18, 1997	August 27, 1997	October 20, 1997
June 9, 1997	July 21, 1997	August 28, 1997	October 22, 1997
June 17, 1997	July 24, 1997	September 3, 1997	October 23, 1997
June 19, 1997	July 25, 1997	September 12, 1997	October 28, 1997
June 20, 1997	July 29, 1997	September 18, 1997	October 30, 1997
June 23, 1997	July 30, 1997	September 19, 1997	November 3, 1997
June 25, 1997	August 5, 1997	September 29, 1997	November 6, 1997
June 30, 1997	August 7, 1997	October 1, 1997	November 7, 1997
July 1, 1997	August 13, 1997	October 2, 1997	
July 7, 1997	August 15, 1997	October 8, 1997	
July 8, 1997	August 20, 1997	October 9, 1997	

The User Fee goal date for this application is November 8, 1997.

This new drug application is indicated for use in combination with other antiretroviral agents for the treatment of HIV infection.

We have completed the review of these aforementioned submissions and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in draft labeling

submitted on November 7, 1997. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on November 7, 1997. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-828. Approval of this submission 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.

Additionally, we acknowledge your commitment to conduct phase 4 studies as stated in your November 6, 1997, letter to the division.

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. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. In addition, we request under 21 CFR 314.81(b)(2)(vii) that you include in your annual report to this application, a status summary of each commitment. 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 material that you propose to use for this product. 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 material and the package insert directly to:

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

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

We acknowledge that validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated.. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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, please contact Christine Kelly, M.S., MBA, RN, Consumer Safety Officer, at (301) 827-2335.

Sincerely yours,

Debra Birnkrant, M.D.
Acting Director
Division of Anti-Viral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research