

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-828 / S-006

Trade Name: Fortovase

Generic Name: (saquinavir)

Sponsor: Hoffman La Roche Inc.

Approval Date: March 18, 1999

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APPLICATION NUMBER:

20-828 / S-006

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Reviews / Information Included in this NDA Review.

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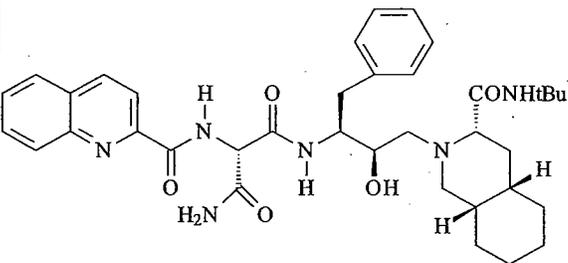
APPROVAL LETTER

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APPLICATION NUMBER:

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CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 20-828			
3. NAME AND ADDRESS OF APPLICANT (City and State) Hoffman-La Roche, Inc. 340 Kingsland Street Nutley, NJ 07110-1199			4. AF NUMBER			
			5. SUPPLEMENT(S)			
			NUMBER(S) SCM-006	DATE(S) 11/17/98		
6. NAME OF DRUG FORTOVASE™ Soft Gelatin Capsules		7. NONPROPRIETARY NAME saquinavir soft gelatin capsules				
8. SUPPLEMENT(S) PROVIDES FOR: The qualification of Roche's Boulder, Colorado facility as an alternative manufacturer for the _____			9. AMENDMENTS / REPORTS Amendment of March 11, 1999			
10. PHARMACOLOGICAL CATEGORY Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)		
13. DOSAGE FORM(S) Soft gelatin capsules		14. POTENCY(IES) 200 mg				
15. CHEMICAL NAME AND STRUCTURE [3S-[2[1R*(R*),2S*],3α,4aβ,8aβ]]-N'[[3-[[[1,1-dimethylethyl)amino]carbonyl]octahydro-2-(1H)-isoquinolinyl]-2-hydroxy-1-(phenylmethyl)propyl]-2-[(2-quinolinylcarbonyl)-amino]butanediamide				16. MEMORANDA		
						
17. COMMENTS See Page 2.						
18. CONCLUSIONS AND RECOMMENDATIONS This CBE Supplement provides for the qualification of Roche's Boulder, Colorado facility as an alternative manufacturer for the _____ This site is currently approved, and has been inspected, for the manufacture of _____ The proposed specifications are the same as the current in-process controls with the addition of specifications for _____ The proposed specifications are reasonable and comprehensive. Satisfactory batch analyses are provided for three batches. Three months of satisfactory accelerated stability data are provided for one batch. In an Amendment of March 11, 1999 the Sponsor agreed to establish a 2 year retest period for this _____ The change is reasonable and supported by adequate data and this Supplement is therefore recommended for approval.						
19. REVIEWER						
NAME George Lunn, Ph.D.		SIGNATURE		DATE COMPLETED		
20. CONCURRENCE: HFD-530/SMiller						
DISTRIBUTION	<input checked="" type="checkbox"/>	Original Jacket	<input checked="" type="checkbox"/>	GLunn	<input checked="" type="checkbox"/>	CKelly
	<input checked="" type="checkbox"/>	Division File	<input checked="" type="checkbox"/>	SMiller	<input checked="" type="checkbox"/>	TNguyen
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