

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-628 / S-015

Trade Name: Invirase

Generic Name: (saquinavir mesylate)

Sponsor: Hoffman-La Roche Inc.

Approval Date: May 11, 2000

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APPLICATION NUMBER:

20-628 / S-015

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Reviews / Information Included in this NDA Review.

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Statistical Review(s)	
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APPROVAL LETTER

NDA 20-628/S-015

Hoffmann-La Roche Inc.
Attention: Cynthia Dillon
Program Director, Drug Regulatory Affairs, CMC
340 Kingsland Street
Nutley, New Jersey 07110-1199

MAY 11 2000

Dear Ms. Dillon:

Please refer to your supplemental new drug application dated January 11, 2000, received January 12, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVIRASE® (saquinavir mesylate) Capsules.

We acknowledge receipt of your submission dated April 27, 2000.

This supplemental new drug application provides for modifications to the drug substance synthesis, a new site for the production of _____

We have completed the review of this supplemental application and it is approved.

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, call Marsha S. Holloman, BS Pharm, JD, Regulatory Project Manager, at (301) 827-2335.

Sincerely yours,



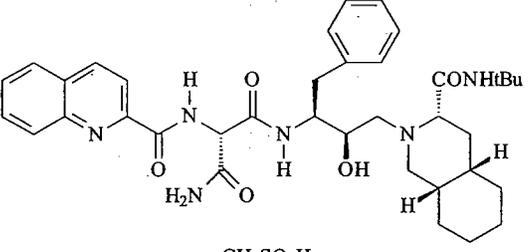
Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530		2. NDA NUMBER 20-628	
3. NAME AND ADDRESS OF APPLICANT (City and State) Hoffman-La Roche Inc. 340 Kingsland Street Nutley, NJ 07110				4. AF NUMBER	
				5. SUPPLEMENT(S)	
				NUMBER(S) SCM-015	DATE(S) 1/11/00
6. NAME OF DRUG INVIRASE® Capsules			7. NONPROPRIETARY NAME saquinavir mesylate capsules		
8. SUPPLEMENT(S) PROVIDES FOR: Modified saquinavir mesylate				9. AMENDMENTS / REPORTS Amendment of 4/27/00	
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) Hard gelatin capsules			14. POTENCY(IES) 200 mg		
15. CHEMICAL NAME AND STRUCTURE [3S-[2[1R*(R*),2S*],3α,4aβ,8aβ]]-N¹[3-[[1,1-dimethylethyl)amino]carbonyl]octahydro-2-(1H)-isoquinolinyl]-2-hydroxy-1-(phenylmethyl)propyl]-2-[(2-quinolinylcarbonyl)-amino]butanediamide monomethanesulfonate salt				16. MEMORANDA	
 <p style="text-align: center;">CH₃SO₃H</p>					
17. COMMENTS See Page 2.					
18. CONCLUSIONS AND RECOMMENDATIONS C J					
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"/> MHolloman
	<input checked="" type="checkbox"/>	Division File	<input checked="" type="checkbox"/>	SMiller	<input checked="" type="checkbox"/> LLewis
	<input checked="" type="checkbox"/>	HFD-830/CChen			

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