

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-685 / S-052

Trade Name: Crixivan

Generic Name: (indinavir sulfate)

Sponsor: Merck & Co.

Approval Date: September 24, 2001

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APPLICATION NUMBER:

20-685 / S-052

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APPLICATION NUMBER:

20-685 / S-060

APPROVAL LETTER



NDA 20-685/S-052

Merck & Co., Inc.
Attention: Michelle W. Kloss, Ph.D.
P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Kloss:

Please refer to your supplemental new drug application dated March 23, 2001, received March 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CRIXIVAN[®] (indinavir sulfate) Capsules, 100 mg, 200 mg, 333 mg, and 400 mg.

We acknowledge receipt of your submission dated June 4, 2001.

This "Changes Being Effectuated in 30 days" supplemental new drug application provides for a change 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 Christine Lincoln, RN, MS, MBA, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

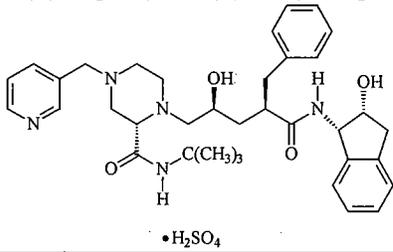
Stephen Paul Miller
9/24/01 10:24:44 PM
20-685 S-052 is approved

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APPLICATION NUMBER:

20-685 / S-060

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW		DUE DATE 9/26/01	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-685	
3. NAME AND ADDRESS OF APPLICANT Merck & Co., Inc. Attn: Michelle W. Kloss, Ph.D. P.O. Box 4, BLA-20 West Point, PA 19486-0004			4. TYPE OF SUPPLEMENT CBE-30		
			5. DOCUMENT(S)		
			NUMBERS SCS-052	DATED 3/23/01	RECEIVED 3/26/01
6. NAME OF DRUG CRIXIVAN™ Capsules			7. NONPROPRIETARY NAME indinavir sulfate capsules		
8. SUPPLEMENT PROVIDES FOR: A change of reagent in Step 3 of the drug substance synthesis.			9. AMENDMENTS/DATES Amendment of 6/4/01		
10. PHARMACOLOGICAL CATEGORY Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> X <input type="checkbox"/> R <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(s)	
13. DOSAGE FORM(S) Capsules			14. POTENCY (CIES) 100 mg, 200 mg, 333 mg, 400 mg		
15. CHEMICAL NAME AND STRUCTURE [1(1S,2R),5(S)]-2,3,5-trideoxy-N-(2,3-dihydro-2-hydroxy-1H-inden-1-yl)-5-[2-[[(- 1,1-dimethylethyl)amino]carbonyl]-4-(3-pyridinylmethyl)-1-piperazinyl]-2-(phenylmethyl)-D-erythro-pentonamide sulfate (1:1) salt			16. MEMORANDA		
 <p>•H₂SO₄</p>					
17. COMMENTS					
<div style="border-left: 1px solid black; border-right: 1px solid black; border-bottom: 1px solid black; width: 100%; height: 100%;"></div>					
18. CONCLUSIONS AND RECOMMENDATIONS This Supplement is therefore recommended for approval.					
19. REVIEWER					
NAME George Lunn, Ph.D.		SIGNATURE [signed electronically in DFS]		DATE OF DRAFT REVIEW 6/21/01	
20. CONCURRENCE: HFD-530/SMiller [signed electronically in DFS]					
DFS CC LIST	<input type="checkbox"/> L	GLunn	<input type="checkbox"/> L	Med: MBaylor	PharmTox
L = Action Letter	<input type="checkbox"/> R	SMiller	<input type="checkbox"/> R	PM: CLincoln	Micro
R = Review	<input type="checkbox"/> R	ONDC3 IO (CChen)	<input type="checkbox"/>	Biopharm	

WITHHOLD 7 **PAGE(S)**

B4 Chemistry Review

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/s/

George Lunn
9/4/01 04:00:55 PM
CHEMIST

Change of reagent in step 3 of DS manufacturing process for Crixivan

Stephen Paul Miller
9/26/01 05:12:15 PM
CHEMIST