CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-685 / S-054

Trade Name: Crixivan

Generic Name: (indinavir sulfate)

Sponsor: Merck & Co.

Approval Date: October 26, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-685 / S-054

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Reviews / Information Included in this NDA Review.

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Medical Review(s)	
Chemistry Review(s)	**X**
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

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APPLICATION NUMBER:

20-685 / S-054

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-685/S-054

Merck & Co., Inc.
Attn: 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 July 3, 2001, received July 6, 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, 400 mg.

We acknowledge receipt of your submission dated October 10, 2001.

This supplemental new drug application provides for designation of an alternate stability testing site for the drug substance (Merck, Wilson, NC), and

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
10/26/01 03:41:29 PM
NDA 20-685 S-054 is approved.

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APPLICATION NUMBER:

20-685 / S-054

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 11/6/01	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
Prior Approval

5. DOCUMENT(S)

NUMBERS	DATED	RECEIVED
SCM-054	7/3/01	7/6/01

6. NAME OF DRUG
CRIXIVAN™ Capsules

7. NONPROPRIETARY NAME
indinavir sulfate capsules

8. SUPPLEMENT PROVIDES FOR:
The designation of an alternate stability testing site for the drug substance and [redacted]

9. AMENDMENTS/DATES
Amendment of 10/10/01

10. PHARMACOLOGICAL CATEGORY
Anti-HIV

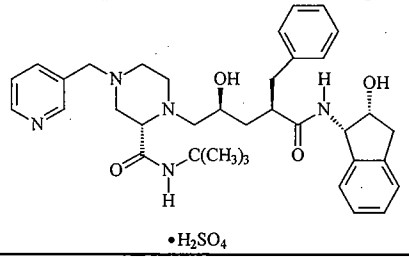
11. HOW DISPENSED
|X| Rx | | OTC

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



$\bullet H_2SO_4$

16. MEMORANDA

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

[redacted]

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
George Lunn, Ph.D.	*[signed electronically in DFS]*	10/22/01

20. CONCURRENCE: HFD-530/SMiller *[signed electronically in DFS]*

DFS CC LIST										
L = Action Letter		L	GLunn		L	Med: MBaylor			PharmTox
R = Review	R	L	SMiller	R	L	PM: CLincoln			Micro
	R	L	ONDC3_IO (CChen)			Biopharm			

WITHHOLD 2 PAGE(S)

B4 Chemistry Review

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/s/

George Lunn
10/24/01 10:57:29 AM
CHEMIST

Indinavir Supplement for change of testing site and

Stephen Paul Miller
11/5/01 03:37:10 PM
CHEMIST