

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**20-685 / S-044**

***Trade Name:*** Crixivan

***Generic Name:*** (indinavir sulfate)

***Sponsor:*** Merck & Co.

***Approval Date:*** April 19, 2001

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*APPLICATION NUMBER:*

**20-685 / S-044**

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### **Reviews / Information Included in this NDA Review.**

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<b>Approvable Letter</b>	
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**APPROVAL LETTER**

NDA 20-685/S044

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

Dear Dr. Kloss:

Please refer to your supplemental new drug application dated December 22, 1999 received December 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CRIVAN™ (indinavir sulfate) Capsules, 100 mg.

This supplemental new drug application provides for a lower strength (100 mg) capsule.

We acknowledge receipt of your amendment dated April 14, 2000.

We have completed the review of this supplemental application and it is approved. Please note that before marketing this product the amended package insert and container labels should be submitted to the efficacy supplement S-043, or to a separate labeling supplement, and approved under that supplement.

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, contact Christine Kelly, RN, MS, MBA, Regulatory Health 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

cc:

NDA-685

HFD-530/Div. Files

HFD-530/C.Kelly

HFD-530/G.Lunn

HFD-530/S.Miller

HFD-830/C.Chen

HFD-095/DDMS-IMT

DISTRICT OFFICE

Drafted by: elw/April 7, 2000

APPROVAL (AP)

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**CHEMISTRY REVIEW(S)**



**WITHHOLD 15 PAGE(S)**

B4 Chemistry Review

/s/

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George Lunn  
4/19/00 01:47:47 PM  
CHEMIST

Review of Crixivan 100 mg Supplement; approved while you were away

Stephen Paul Miller  
11/17/00 11:33:10 AM  
CHEMIST