



Food and Drug Administration  
Rockville MD 20857

NDA 20-685/S-046 and S-047

Merck & Co., Inc.  
Attention: Sandra Rattray, Ph.D.  
Associate Director, Regulatory Affairs  
P.O. Box 2000, RY 33-720  
Rahway, NJ 07065

Dear Dr. Rattray:

Please refer to your supplemental new drug applications dated June 20, 2003, received June 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan® (indinavir sulfate) capsules.

We acknowledge receipt of your submissions dated October 27, 2003, February 6, 2004, and February 24, 2004.

This supplemental new drug application provides for the following changes:

1. Revisions to the Clinical Pharmacology, Warnings, Precautions, and Dosage and Administration sections of the package insert.
2. Revisions to the "Can Crixivan be taken with other medications?" and "What are the possible side effects of Crixivan?" sections of the patient package insert.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-685/S-046

and S-047." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

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 Virginia L. Behr, Chief, Project Management Staff, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Enclosure: approved draft labeling (package insert and patient package insert).

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/s/

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Jeffrey Murray  
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