DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-685/S-060 **PRIOR APPROVAL SUPPLEMENT**

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 application dated May 14, 2004, received May 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan® (indinavir sulfate) capsules.

This supplemental new drug application provides for the following changes to the package insert:

1. The **CLINICAL PHARMACOLOGY**: Pharmacokinetics: *Pregnant Patients* section was updated to include information from a study (PACTG 358) of 16 HIV infected pregnant patients at 14 to 28 weeks gestation at enrollment. An optimal dosing regimen has not been established.

2. The **PRECAUTIONS**: Pregnancy: *Pregnancy Category C* section was also revised to include information from Study PACTG 358.

We have completed the review of this supplemental application, 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-060." 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).

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

/s/

Debra Birnkrant
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NDA 20-685