DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-685/S-062 **CHANGES BEING EFFECTED**

Merck and Company, Inc.
Attention: Mary Beth Wigley, Manager, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Ms. Wigley:

Please refer to your supplemental new drug application dated June 29, 2006, received June 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan™ (indinavir sulfate) capsules. This "Changes Being Effected" supplemental new drug application adds text to the labeling regarding renal insufficiency.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 29, 2006.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Behr, Chief, Project Management Staff, at (301) 796-0675.

Sincerely,

{See appended electronic signature page}

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

Enclosure: approved labeling (package insert and patient 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/

Jeffrey Murray
8/7/2006 04:58:20 PM