



NDA 20-685/S-061

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 Mary Beth:

Please refer to your supplemental new drug application dated June 16, 2004, received June 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan[™] (indinavir sulfate) capsules.

We acknowledge receipt of your amendments dated November 23, 2005 and December 9, 2005.

This "Changes Being Effected" supplemental new drug application provides for the addition of drug interactions to the PRECAUTIONS section of the labeling (package insert) in response to a request from the FDA and in response to changes in the Effexor[®] (venlafaxine) package insert.

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 16, 2005.

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, HFD-410
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.

CRIXIVAN® (indinavir sulfate) Capsules

If you have any questions, call Monica Zeballos, Pharm.D., Regulatory Project Manager, at (301) 796-0840.

Sincerely yours,

{ See appended electronic signature page }

Jeff Murray, M.D., M.P.H.
Deputy 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
1/12/2006 04:57:53 PM