



NDA 20-685/S-064

CHANGES BEING EFFECTED

Merck & Co., Inc.
Attention: Karen Henry
Associate Manager, Regulatory Affairs
UG2C-50, P.O. Box 1000
North Wales, PA 19454-1099

Dear Ms. Henry:

Please refer to your supplemental new drug application dated January 18, 2007, received January 19, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan[™] (indinavir sulfate) capsules 100/200/333/400mg.

We acknowledge receipt of your submission dated June 15, 2007, received June 18, 2007.

This "Changes Being Effected" supplemental new drug application adds renal failure to the Adverse Reactions section of the package insert and adds U.S. Patent Numbers to the package insert and the patient 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 January 18, 2007.

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 Anne Marie Russell, Ph.D., Regulatory Project Manager, at (301) 796-2014.

Sincerely,

{ See appended electronic signature page }

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

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/

Debra Birnkrant
7/18/2007 03:17:35 PM
NDA 20-685