DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-685/S-065 **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 October 15, 2007, received October 16, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan™ (indinavir sulfate) capsules 100 mg, 200 mg, 333 mg and 400 mg.

This "Changes Being Effected" supplemental new drug application adds rosuvastatin to the Warnings and Drug-Drug Interaction sections of the package insert and updates the patient package insert to advise that Crestor (rosuvostatin) is not a medicine to be taken with Crixivan™ .

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 15, 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}
Debra Birnkrant, M.D.
Director, Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: 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
4/16/2008 12:31:08 PM
NDA 20-685