DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-685/S-068

Merck & Co., Inc.
Attention: Karen L. Henry
Associate Manager, Worldwide 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 and received November 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Crixivan® (Indinavir Sulfate).

This "Changes Being Effected" supplemental new drug application provides for revisions to the USPC and USPPI to include a precaution regarding the co-administration of rosuvastatin. The USPC was updated to include a statement regarding the unknown interaction of indinavir with pravastatin or fluvastatin in the WARNINGS and PRECAUTIONS sections of USPC, and the CLINICAL PHARMACOLOGY sections was updated to include corrected data regarding itraconazole, ketoconazole and vardenafil.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed labeling.

CONTENT OF LABELING
The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient prescribing information).

PROMOTIONAL MATERIALS
You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more

information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

REPORTING REQUIREMENTS
We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Robert G. Kosko, Jr., Pharm.D., M.P.H., Regulatory Project Manager, at (301) 796-3979.

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 (Clean copy of approved label)

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

/s/

Kendall Marcus

12/10/2008 11:22:21 AM