DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-145/S-003

Merck & Co., Inc.
Attention: Robert A. Fromtling, Ph.D.
Director, Worldwide Regulatory Affairs
126 E. Lincoln Ave.
P.O. Box 2000, RY33-212
Rahway, New Jersey 07065-0900

Dear Dr. Fromtling:

Please refer to your supplemental new drug application dated May 1, 2008, received May 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ISENTRESS™ (raltegravir potassium) 400 mg tablets.

We also acknowledge receipt of your submissions dated May 13, 2008 and June 10, 2008.

This "Changes Being Effected" supplement provides for the following changes:

- Revisions to the U.S package insert, **Postmarketing Experience** subsection, to include postmarketing adverse reaction terms rash and Stevens-Johnson syndrome.

- Revisions to the U.S. patient package insert to include rash and severe skin reactions under **What are the possible side effects of ISENTRESS**

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 content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on May 1, 2008.

In addition, within 21 days of the date of this letter, amend any pending applications for these NDAs with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Amalia Himaya, Regulatory Project Manager, at (301) 796-3391.

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: labeling

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

10/24/2008 01:37:50 PM