



NDA 22-145/S-006

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 November 24, 2008, received November 24, 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 submission dated December 16, 2008.

This “Changes Being Effectuated” supplement provides for the following changes:

- Revisions to the U.S package insert, **Postmarketing Experience** subsection, to include adverse reaction terms depression, suicidal ideation and behaviors.
- Revisions to the U.S. patient package insert, **What are the possible side effects of ISENTRESS** section, to include depression, suicidal thoughts and actions.

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 November 24, 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

1/13/2009 09:55:01 AM