DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993-0002

NDA 22-145/S-004

Merck & Co., Inc.
Attention: Robert A. Fromtling, Ph.D.
Director, Worldwide Regulatory Affairs
126 E. Lincoln Avenue
P.O. Box 2000, RY 33-212
Rahway, NJ 07065-0900

Dear Dr. Fromtling:

Please refer to your supplemental new drug application dated September 25, 2008, received September 26, 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 January 12, 2009, January 21, 2009, January 29, 2009, January 30, 2009, February 9, 2009, February 24, 2009, March 4, 2009, April 10, 2009, May 7, 2009, May 8, 2009, May 15, 2009, June 12, 2009, June 19, 2009, and June 26, 2009.

This supplemental new drug application provides for the use of ISENTRESS® (raltegravir potassium) tablets in combination with other antiretrovirals for the treatment of HIV-1 infection in treatment-naive adult patients.

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 agreed-upon labeling text.

Approval of this supplement fulfills the following postmarketing commitment acknowledged in our October 12, 2007, approval letter:

6. Submit Week 48 report and datasets for Protocol 021.

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (text for the package insert and patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission **"SPL for approved supplement NDA 22-145/S-004."**

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

PROMOTIONAL MATERIALS
In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division, the Division of Antiviral Products, and two copies of both the promotional materials and the package insert directly 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

LETTERS TO HEALTH CARE PROFESSIONALS
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

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 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 (Package and Patient Package Inserts)

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
7/8/2009 04:33:28 PM
NDA 22-145