DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-145/S-001

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 March 31, 2008, received March 31, 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 30, 2008, June 3, 2008, July 10, 2008, July 14, 2008, July 18, 2008, July 25, 2008, August 21, 2008, September 9, 2008 September 10, 2008, September 18, 2008, October 1, 2008, October 15, 2008, October 23, 2008, November 14, 2008, November 20, 2008, November 25, 2008, December 11, 2008, January 7, 2009, January 9, 2009, January 16, 2009, and January 21, 2009.

This supplemental new drug application updates the package insert and patient package insert with the 48 week data from Studies 018 and 019 to support the use of ISENTRESS® (raltegravir potassium) 400 mg tablets for the treatment of HIV-1 infection, in combination with other antiretroviral agents, in treatment-experienced adult patients.

We also refer to your submissions dated July 23, 2008, and August 13, 2008, containing the mouse and rat carcinogenicity final study reports, respectively. As conveyed to you via facsimile dated September 4, 2008, the data from these submissions will be used to update the NONCLINICAL TOXICOLOGY section of the package insert submitted with this supplement.

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.

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. 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-001."

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).

ACCELERATED APPROVAL – SUBPART H REQUIREMENTS
We approved this NDA under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitments made under 21 CFR 314.510.

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
1/29/2009 12:14:34 PM
NDA 22-145