



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 (sNDA 22-145/S001) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ISENTRESS (raltegravir potassium) 400 mg tablets. We also refer to the January 29, 2009, approval letter.

The package insert included in the January 29, 2009, approval letter requires revisions to the Highlights of Prescribing Information section. Specifically, we failed to update the Recent Major Changes section, with the revision date of "01/2009" for the Indication and Usage and Dosage and Administration information.

Please be advised you will receive a replacement action letter containing the above revisions to the package insert. Please note the date of the action will be unchanged, but the signature time will be one minute later to permit differentiation between the letters.

If you have any questions, call Amalia Himaya, Regulatory Project Manager, at (301) 796-3391.

Sincerely,

{See appended electronic signature page}

Karen Winestock
Chief, Project Management Staff
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

Karen Winestock
1/30/2009 03:36:04 PM