



NDA 22-145/S-011
NDA 22-145/S-012

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
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 Applications (sNDAs) dated August 31, 2009, received September 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ISENTRESS™ (raltegravir potassium) tablets, 400 mg.

We also acknowledge receipt of your submissions dated September 18, 2009¹, November 6, 2009, November 25, 2009, December 16, 2009, January 20, 2010, February 18, 2010, March 1, 2010, March 19, 2010, April 15, 2010, May 28, 2010, and June 15, 2010.

These Prior Approval supplemental new drug applications propose to update the U.S. package insert and patient package insert with the 96-week data from Protocols 018 and 019 (treatment-experienced patients) and Protocol 021 (treatment-naïve patients) to support the use of ISENTRESS™ (raltegravir potassium) tablets in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert and patient package insert) and include the labeling changes proposed in any pending “Changes Being Effectuated” (CBE)

¹ NDA 22-145/S-012 only

supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending “Changes Being Effected” (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
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 or (301) 796-1500.

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:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22145	SUPPL-12	MERCK SHARP AND DOHME CORP	ISENTRESS
NDA-22145	SUPPL-11	MERCK SHARP AND DOHME CORP	ISENTRESS

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/s/

DEBRA B BIRNKRANT
06/29/2010