



sNDA 22145/S-30
sNDA 203045/S-8

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Chitrananda Abeygunawardana, PhD
Director, Global Regulatory Affairs
351 North Sumneytown Pike
UG2D-68
P.O. Box 1000
North Wales, PA 19454

Dear Dr. Abeygunawardana:

Please refer to your Supplemental New Drug Applications (sNDA) dated April 24, 2013, received April 25, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ISENTRESS[®], (raltegravir) film-coated tablets, 400 mg and ISENTRESS[®] (raltegravir) chewable tablets, 25 mg and 100 mg.

We acknowledge receipt of your amendments dated July 10, 2013, August 19, 2013, and October 21, 2013 (2).

These "Prior Approval" supplemental new drug applications propose to update the labeling with drug-drug interaction information when raltegravir is used in combination with calcium carbonate-containing antacids or magnesium and/or aluminum-containing antacids.

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 the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert and text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 that includes labeling changes for these NDAs, including 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Karen Winestock, Chief, Project Management Staff, at (301) 796-0834 or 301-796-1500.

Sincerely,

{See appended electronic signature page}

Kendall A. Marcus, MD
Deputy Director of Safety
Division of Antiviral Products
Office of Antimicrobial Product
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of 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 A MARCUS
10/24/2013