DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA22145/S-032
NDA 203045/S-010
NDA 205786/S-01

SUPPLEMENT APPROVAL

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

Dear Dr. Abeygunawardana:

Please refer to your Supplemental New Drug Applications (sNDA) for NDA 203045 and NDA 22145 dated October 11, 2013, and NDA 205786 dated February, 24, 2014 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ISENTRESS® (raltegravir) film-coated tablets, 400 mg, ISENTRESS® (raltegravir) chewable tablets, 25 mg and 100 mg, and ISENTRESS® (raltegravir) for oral suspension, 100 mg.

We acknowledge receipt of your amendments on the following dates:

NDAs 22145 and 203045

November 7, 2013	February 24, 2014	March 25, 2014
January 16, 2014	March 5, 2014	March 31, 2014

NDA 205786

February 24, 2014	March 5, 2014	March 25, 2014
March 31, 2014		

These prior approval supplemental new drug applications propose to update the DRUG INTERACTIONS, Effect of Raltegravir on the Pharmacokinetics of Other Agents, DRUG INTERACTIONS, Effect of Other Agents on the Pharmacokinetics of Raltegravir (Table 8), and CLINICAL PHARMACOLOGY, Table 10 sections of the labeling with drug interaction information for boceprevir and/or telaprevir.

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, text for the patient package insert, Medication Guide), 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 Nina Mani, Regulatory Project Manager, at (240) 402-0333 or the Division's main number at (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
04/08/2014