DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022145/S-039

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Attention: Paula Hines, Ph.D.
Director, Global Regulatory Affairs and Clinical Safety
351 North Sumneytown Pike, P.O. Box 1000, UG2D-68
North Wales, PA 19454

Dear Dr. Hines:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 4, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Isentress HD® (raltegravir) film-coated tablets, 400 mg.

We also refer to our approval letter dated March 26, 2018, in which we erroneously stated Isentress HD® (raltegravir) film-coated tablets, 600 mg, which should state the drug product strength as 400 mg. This replacement letter incorporates the correction of this error. The effective date will remain March 26, 2018, the date of the original approval letter.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of a new manufacturing site for the drug product, MSD International GmbH, 70 Tuas West Drive, Singapore 638414, FEI#3004199021 and the following associated manufacturing process changes:

- (b) (4)
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APPROVAL

We have completed our review of this supplemental new drug application. This supplement is approved.

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 Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD.
Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
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