DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202258/S-011

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corporation
Attention: Thomas J. Chambers, MD
Director, Global Regulatory Affairs
351 North Sumneytown Pike, PO Box 1000, UG2D-68
North Wales, PA 19454-2505

Dear Dr. Chambers:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 14, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VICTRELIS® (boceprevir) 200 mg capsules.

We acknowledge receipt of your amendments dated July 8, 2013, July 10, 2013, August 2, 2013, September 13, 2013, September 24, 2013, September 30, 2013, November 8, 2013, November 27, 2013, December 4, 2013, January 31, 2014, February 19, 2014, March 10, 2014 and March 28, 2014.

This "Prior Approval" supplemental new drug application was submitted to update the Clinical Studies section of the Package Insert with the final study report for clinical trial P05514, entitled "A Single-Arm Study to Provide Boceprevir Treatment in Subjects with Chronic Hepatitis C Genotype 1 Deemed Nonresponders to Peginterferon/Ribavirin in Previous Schering-Plough Boceprevir Studies (PROVIDE)."

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is 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 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 this NDA, 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 numbers and annual report dates.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

FULFILLMENT OF POSTMARKETING COMMITMENT

The approval of this supplement fulfills the following postmarketing commitment listed in the May 13, 2011, approval letter:

1767-15 Submit the final report and datasets for Study P05514 (PROVIDE), an open label ongoing efficacy trial in which boceprevir treatment in combination with peginterferon alfa and ribavirin is provided to subjects with chronic hepatitis C genotype 1 who did not respond to the peginterferon alfa and ribavirin control in previous boceprevir trials.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Victoria Tyson, Regulatory Project Manager, at (301) 796-0827.

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

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

/s/

DEBRA B BIRNKRANT
04/09/2014