DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202258/S-001

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corporation
Attention: Thomas J. Chambers, MD
Director, Global Regulatory Affairs
PO Box 1000, UG2D-68
North Wales, PA 19454-1099

Dear Dr. Chambers:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 30, 2012, 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 February 16, 2012, May 3, 2012 and July 27, 2012.

This "Prior Approval" supplemental new drug application provides for revisions to the Drug Interactions and the Use in Specific Populations sections of the Package Insert to include information on drug-drug interactions of boceprevir with cyclosporine, tacrolimus, escitalopram, atorvastatin and pravastatin. This drug-drug interaction information was added to the "What should I tell my healthcare provider before taking VICTRELIS®" section of the Medication Guide.

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 inset and 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 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.

POSTMARKETING REQUIRMENTS UNDER 505(o)

We note that you have fulfilled the following Postmarketing Requirement established in the May 13, 2011, approval letter for NDA 202258:

1767-10 Conduct an *in vivo* drug-drug interaction trial between boceprevir and a selective Serotonin reuptake inhibitor (SSRI) (e.g. escitalopram).

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We note that you have fulfilled the following Postmarketing Commitments established in the May 13, 2011, approval letter for NDA 202258:

1767-11 Conduct an *in vivo* drug-drug interaction trial between boceprevir and tacrolimus.

1767-12 Conduct an *in vivo* drug-drug interaction trial between boceprevir and cyclosporine.

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}

/Kendall Marcus M.D./
for 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/

KENDALL A MARCUS
07/30/2012