DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 207931/S-004

SUPPLEMENT APPROVAL

AbbVie Inc.
Attention: Glen Spears, PhD
Director, Regulatory Affairs
1 N. Waukegan Road
Dept. PA77/Bldg. AP30
North Chicago, Illinois 60064

Dear Dr. Spears:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on December 7, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TECHNIVIE (ombitasvir, paritaprevir and ritonavir) tablets.

This Prior Approval supplemental new drug application provides for the following revisions:

- Updates to Section 4 (CONTRAINDICATIONS); Table 2 (Drugs that are Contraindicated with TECHNIVIE); including the following drug classes: Anti-anginal, Antiarrhythmic, Antipsychotic, GI Motility Agents, and Neuroleptics

- Additions/revisions to Sections 7.3 (Established and Other Potential Drug Interactions); Table 4 **(**Established Drug Interactions Based on Drug Interaction Trials); including updates to the Anti-Diabetics, Muscle relaxants, Narcotic Analgesic and Sedatives/Hypnotics agents

- Updates to Section 7.4 (Drugs without Clinically Significant Interactions with TECHNIVIE)

- Updates to section 12.3 (Pharmacokinetics); including the pharmacokinetic properties of the components of TECHNIVIE

- Revisions to Section 12.4 (Microbiology); including the Mechanism of Action and Antiviral Activity sections for the individual components of TECHNIVIE

- Revisions to Section 13 (NON CLINICAL TOXICOLOGY) to add information from a completed 104-week rat carcinogenicity study evaluating ombitasvir

- Revisions to Section 17 (PATIENT COUNSELING INFORMATION); including revisions to the Pregnancy and Administration sections and the removal of the Hepatitis C Virus Transmission and Missed Dose sections

- Corresponding changes to the Medication Guide for drug-drug interactions and administration

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 and with the following additional revisions listed below and indicated in the enclosed labeling.

- Table 4 of Section 7.3 (Pharmacokinetics) was changed to reflect the following language as agreed upon via email communication dated June 17, 2016 in response to the information request dated June 16, 2016:

  Monitor for signs of onset of lactic acidosis such as respiratory distress, somnolence, and non-specific abdominal distress or worsening renal function. Concomitant metformin use in patients with renal insufficiency or hepatic impairment is not recommended. Refer to the prescribing information of metformin for further guidance.

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 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 number(s) and annual report date(s).

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.

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:

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

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf).

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 Alicia Moruf, PharmD, MPH, Regulatory Project Manager, at (301) 796-3953.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director, Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

POONAM MISHRA
06/21/2016