NDA 209195/S-004

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Hilary White
Associate II, Regulatory Affairs
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. White:

Please refer to your supplemental new drug application (sNDA), dated and received on March 19, 2019 for VOSEVI® (sofosbuvir, velpatasvir, and voxilaprevir) tablets, 400mg/100mg/100mg, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA).

This Prior Approval supplemental new drug application provides for the following changes to the US Prescribing Information (USPI):

- Addition of new subsection 5.2 under the WARNINGS AND PRECAUTIONS regarding the risk of hepatic decompensation/failure in patients treated with HCV NS3/4A protease inhibitor containing direct acting antiviral (DAA) regimens, including treatment with VOSEVI
- Update ADVERSE REACTIONS, Postmarketing Experience subsection 6.2 with hepatic decompensation/failure with NS3/4A protease inhibitor-containing regimens
- Update the DRUG INTERACTIONS Section, 7.3 subsection with information regarding the risk of dysglycemia in patients with diabetes
- Update the USE IN SPECIFIC POPULATIONS, subsection 8.7 with the information regarding postmarketing cases of hepatic decompensation/failure
- Update the PATIENT COUNSELING INFORMATION Section and the Patient Information to be consistent with the USPI

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert), 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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 Kyong Hyon, Safety Regulatory Project Manager, at 301-796-0734.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
09/27/2019 04:28:25 PM
on behalf of Debra Birnkrant