DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021356/S-055
NDA 022577/S-011

SUPPLEMENT APPROVAL

Gilead Sciences Inc.
Attention: Alison Blaschke, MBS, RAC
Regulatory Affairs Associate II
333 Lakeside Drive
Foster City, CA 94404

Dear Ms. Blaschke:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on October 7, 2016, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIREAD® (tenofovir disoproxil fumarate) tablets, for oral use and VIREAD® (tenofovir disoproxil fumarate) powder, for oral use.

These Prior Approval supplemental new drug applications provide for the following revisions to labeling:

- Removal of information related to lactic acidosis/severe hepatomegaly with steatosis from the Boxed Warning
- Revision of information in WARNINGS AND PRECAUTIONS (Section 5) related to lactic acidosis/severe hepatomegaly with steatosis
- Addition of DESCOVY, ODEFSEY, GENVOYA, and VEMLIDY to the list of drugs that should not be used in combination with VIREAD in INDICATIONS AND USAGE (Section 1) and Subsection 5.4 Coadministration with Other Products
- Addition of warning not to administer VIREAD with TAF-containing products in WARNINGS AND PRECAUTIONS (Section 5)
- Removal of fat redistribution warning from WARNINGS AND PRECAUTIONS (Section 5)
- Addition of drug-drug interaction information in DRUG INTERACTIONS (Section 7), CLINICAL PHARMACOLOGY (Section 12) to harmonize with the approved Epclusa® (sofosbuvir/velpatasvir) and Harvoni® (ledipasvir/sofosbuvir) labels
- Corresponding changes to PATIENT COUNSELING INFORMATION (Section 17) and Patient Information

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

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 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 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 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 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 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.

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

ENCLOSURE(S):
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/

POONAM MISHRA
04/07/2017
on behalf of Debra Birnkrant, MD