



NDA 021356/S-056
NDA 022577/S-012

SUPPLEMENT APPROVAL

Gilead Sciences, Inc.
Attention: Linda Fletcher, PharmD
Regulatory Affairs Associate II
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Fletcher:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received on March 9, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VIREAD[®] (tenofovir disoproxil fumarate) tablets and VIREAD[®] (tenofovir disoproxil fumarate) powder.

These Prior Approval supplemental new drug applications provide for the following changes to the US Prescribing Information (USPI):

- Updates to the DRUG INTERACTIONS section regarding the drug-drug interaction information for VOSEVI[®] (sofosbuvir/velpatasvir/voxilaprevir) to align with VOSEVI[®] USPI; in addition, formatting changes were made to remove subsections and to present information in a table format
- Updates to the INDICATIONS and USAGE, WARNINGS AND PRECAUTIONS, and PATIENT COUNSELING INFORMATION sections with the addition of BIKTARVY[®] (bictegravir, emtricitabine, and tenofovir alafenamide) to the list of drugs not to be used in combination with VIREAD[®] to align with recently approved BIKTARVY[®] USPI

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.

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 (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 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).

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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
07/30/2018
on behalf of Debra Birnkrant, MD