



NDA 021896/S-26
NDA 021500/S-29

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 June 28, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EMTRIVA[®] (emtricitabine) oral solution 10 mg/ml and EMTRIVA[®] (emtricitabine) capsules 200 mg.

These Prior Approval supplemental new drug applications provide for the following changes to the EMTRIVA[®] USPI:

- Addition of subsection 2.1, Testing Prior to Initiation of Treatment with EMTRIVA: Prior to or when initiating EMTRIVA test for hepatitis B virus infection, to DOSAGE AND ADMINISTRATION
- Removal of subsection 5.3, Coadministration with Related Products, from WARNINGS AND PRECAUTIONS
- Revisions to section 8, USE IN SPECIFIC POPULATIONS, to conform with the Pregnancy and Lactation Labeling Rule (PLLR)
- Removal of no known antidote language to section 10, OVERDOSAGE
- Addition of information regarding the antiretroviral pregnancy registry and lactation instructions to section 17, PATIENT COUNSELING INFORMATION
- Editorial and formatting revisions throughout the USPI to conform with best labeling practices and align with recently approved HIV antiretroviral USPIs.
- Editorial and formatting revisions to the Patient Package Insert (PPI) to conform to best labeling practices and be consistent with the USPI.

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 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 <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, 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 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).

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If you have any questions, call Alicia Moruf, PharmD, MPH, Regulatory Project Manager, at 301-796-3953 or (301)796-1500.

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
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
12/10/2018
on behalf of Debra Birnkrant