



NDA 021752/S-060

SUPPLEMENT APPROVAL

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

Dear Dr. Fletcher:

Please refer to your supplemental new drug application (sNDA) dated and received on March 27, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TRUVADA[®] (emtricitabine and tenofovir disoproxil fumarate) tablets, for oral use.

This Prior Approval supplemental new drug application provides for proposed modifications to the approved emtricitabine/tenofovir disoproxil fumarate Single Shared System (SSS) REMS. We acknowledge that your application included a rationale to support the proposed REMS modifications.

APPROVAL

We have completed our review of this application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for TRUVADA[®] (emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg) for a pre-exposure prophylaxis (PrEP) indication was originally approved on July 16, 2012, and the SSS REMS for emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg was approved on June 8, 2017. The REMS consists of elements to assure safe use (ETASU) and a timetable for submission of assessments of the REMS. Your proposed modification to the SSS REMS consists of eliminating the ETASU, including educational and training materials.

Elements to Assure Safe Use: We have determined that elements to assure safe use are no longer necessary because:

- Since approval, non-REMS educational programs (e.g., Centers for Disease Control and Prevention and local health departments; Department of Health and Human Services initiative) and clinical guidelines for PrEP have become readily available and support greater awareness, education, and knowledge of PrEP

among healthcare professionals (HCPs), PrEP users, and public health communities. These materials and guidelines convey:

- the importance of strict adherence to the recommended dosing schedule
- importance of regular monitoring of HIV-1 serostatus to avoid continuing to take emtricitabine/tenofovir disoproxil fumarate alone if seroconversion has occurred
- that emtricitabine/tenofovir disoproxil fumarate for a PrEP indication should only be used as part of a comprehensive prevention strategy that includes other preventive measures
- The REMS assessments have been completed and the available information indicates that prescribers and uninfected individuals understand the important key messages with regards to appropriate use of emtricitabine/tenofovir disoproxil fumarate for a PrEP indication.

Therefore, because the elements to assure safe use are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for emtricitabine/tenofovir disoproxil fumarate tablets, for oral use.

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

/s/

DEBRA B BIRNKRANT
07/01/2019 12:20:11 PM