ANDA 209721/S-001

PRIOR APPROVAL SUPPLEMENT APPROVAL

Amneal Pharmaceuticals Company GmbH
Amneal Pharmaceuticals of New York, LLC
50 Horseblock Road
Brookhaven, New York 11719

Attention: Candis Edwards
Senior Vice President, Regulatory Affairs
U.S. Agent for Amneal Pharmaceuticals Company GmBH

Dear Madam:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on May 21, 2019, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 100 mg/150 mg, 133 mg/200 mg, 167 mg/250 mg, and 200 mg/300 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as Prior Approval Supplement, provides for proposed modifications to the approved emtricitabine and tenofovir disoproxil fumarate Single Shared System (SSS) REMS.

We have completed the review of this sANDA, as amended, and it is **approved**.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

Your proposed modification to the emtricitabine and tenofovir disoproxil fumarate SSS REMS consists of eliminating the elements to assure safe use (ETASUs), 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., CDC and local health departments; HHS 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 comprehensive prevention strategy that include 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 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.

REPORTING REQUIREMENTS

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98 and at section 506I of the FD&C Act. The Agency should be advised of any change in the marketing status of this drug or if this drug will not be available for sale after approval. In particular, under section 506I(b) of the FD&C Act, you are required to notify the Agency in writing within 180 days from the date of this letter if this drug will not be available for sale within 180 days from the date of approval. As part of such written notification, you must include (1) the identity of the drug by established name and proprietary name (if any); (2) the ANDA number; (3) the strength of the drug; (4) the date on which the drug will be available for sale, if known; and (5) the reason for not marketing the drug after approval.

ANNUAL FACILITY FEES

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions[1] with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts.

[1] Some of these provisions were amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II) (Public Law 115-52, Title III).

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

If you have any questions, call Chantal Phillips, REMS Coordinator Lead, at (301) 796-2259.

Sincerely,

{See appended electronic signature page}

Kimberly Witzmann, MD
Acting Deputy Director
Office of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

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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/

KIMBERLY A WITZMANN
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