NDA 213509

TENTATIVE APPROVAL

Mylan Pharmaceuticals Inc., a Viatris Company
Attn: Robert A. Barto, Senior Director, Regulatory Affairs
US Agent for Mylan Laboratories Limited, a Viatris Company
3711 Collins Ferry Road
Morgantown, WV 26505

Dear Mr. Barto:

Please refer to your new drug application (NDA) dated and received February 4, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for Efavirenz, Emtricitabine, and Tenofovir Alafenamide Tablets, 400 mg/200 mg/25 mg.

We acknowledge receipt of your amendment dated October 3, 2023, which constituted a complete response to our November 25, 2020, action letter.

This NDA proposes the use of Efavirenz, Emtricitabine, and Tenofovir Alafenamide Tablets as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 35 kg.

This NDA was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR).

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105(a); therefore, this application is not approved and will not be approved until FDA issues an approval letter after any necessary additional review of the application. Enclosed are the tentatively approved labeling (text for the Prescribing Information, Medication Guide, and container labeling). Based on the data provided, the expiration dating period is 24 months for Efavirenz, Emtricitabine, and Tenofovir Alafenamide Tablets, 400 mg/200 mg/25 mg in HDPE bottles containing 30 tablets with desiccant and non-child-resistant cap when stored below 30ºC (86ºF). This tentative approval determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted before the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved, and cannot be legally marketed and the use of the enclosed tentatively approved labeling is not permitted for marketing this drug product. If you believe that there are grounds for issuing the final approval letter before the expiration of the patent(s) and/or exclusivity protection, you should amend your application accordingly.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names (*April 2016*)*[1]*,* guidance for industry *Best Practices in Developing Proprietary Names for Human Prescription Drug Products* (December 2020), and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)[2]

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We note that if this application is ultimately approved, you will need to meet these requirements.

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] https://www.fda.gov/media/151712/download

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[3].

OTHER

We also remind you that you are expected to comply with the reporting requirements provided in 21 CFR 314.80 and 314.81. If the product is to be mass distributed in developing countries, a system of collecting and reporting adverse drug reactions by the distributor would be desirable (e.g., through governmental or nongovernmental agencies distributing the products).

If you have any questions, call David Araojo, Pharm.D., Program Coordinator, at (301) 796-0669.

Sincerely,

{See appended electronic signature page}

Sarita Boyd, Pharm.D.
Associate Director for PEPFAR
Division of Antivirals
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S): (tentatively approved)

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Container Labeling

[3] https://www.uspnf.com/

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/

SARITA D BOYD
03/22/2024 11:32:52 AM