NDA 215448

TENTATIVE APPROVAL

Aurobindo Pharma USA, Inc.
U.S. Agent for Aurobindo Pharma Limited, India
Attention: Blessy Johns
Director, Regulatory Affairs
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Dear Ms. Johns:

Please refer to your new drug application (NDA) dated and received December 30, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for (FD&C Act) for the following drug product:

- Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg.

We acknowledge receipt of your amendment dated November 28, 2022, which constituted a complete response to our October 14, 2022, action letter.

This NDA proposes the use of Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablets, 50 mg/200 mg/25 mg (b) (4)

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, it is not approved and will not be approved until FDA issues an approval after any necessary additional review of the NDA. Enclosed is the tentatively approved submitted labeling (Prescribing Information submitted May 25, 2023, Patient Package Insert submitted May 24, 2023, container labeling submitted May 24, 2023) with minor revisions listed below. (b) (4)

Minor Revisions for the Prescribing Information

(b) (4)

(b) (4)

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. 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. This amendment should include draft final printed labels and labeling which comply with all U.S. regulations (uniqueness of drug product appearance per 21 CFR 206; child-resistant packaging per 16 CFR 1700, etc.). 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.

This drug product is not approved and cannot be legally marketed in the United States until you have been notified in writing that this NDA is approved. The use of the enclosed tentatively approved labeling is not permitted for U.S. marketing this drug product.

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 2018 through 2022*.)[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.

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 Monica Zeballos, Pharm.D., Sr. Program Consultant, at (301) 796-0840.

Sincerely yours,

{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)

[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

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Container 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/

SARITA D BOYD
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