NDA 213681

TENTATIVE APPROVAL

Laurus Generics, Inc.
U.S. Agent for Laurus Labs Limited, India
Attention: Sharath Koripally
Senior Director RA, QA & PV
400 Connell Drive, Suite 5200
Berkeley Heights, NJ 07922

Dear Mr. Koripally:

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 the following drug product:

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

We acknowledge receipt of your amendments dated February 23, 2022, and April 12, 2023, which constituted complete responses to our February 17, 2022, and November 21, 2022, complete response letters, respectively.

We acknowledge receipt of your major amendment dated May 27, 2022, which extended the goal date by three months.

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

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

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 are the tentatively approved labeling (text for the Prescribing Information, Patient Package Insert, container labeling) with minor revisions listed below. (b) (4)

(b) (4)

Minor Revisions for the Prescribing Information

(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 and/or exclusivity. Therefore, final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] 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 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.

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

[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

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

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)

- 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
10/12/2023 12:46:02 PM