



NDA 210796

**TENTATIVE APPROVAL**

AB Pharmaceuticals, LLC  
Attention: Andrej Gasperlin, President  
U.S. Agent for Macleods Pharmaceuticals Limited, India  
17471 Highland Way Drive  
Chesterfield, MO 63005

Dear Mr. Gasperlin:

Please refer to your New Drug Application (NDA) dated and received November 3, 2017, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for the following drug product:

- Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate Tablets, 50 mg/300 mg/300 mg

We acknowledge receipt of your amendment dated September 25, 2018, which constituted a complete response to our April 26, 2018, action letter.

This NDA provides for the use of Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate Tablets (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 for use as recommended in the agreed-upon enclosed labeling (text for the Prescribing Information, Patient Package Insert, container labeling) submitted on March 14, 2019. Based on the data provided, the expiration dating period is (b) (4) for Dolutegravir, Lamivudine, and Tenofovir Disoproxil Fumarate Tablets, 50 mg/300 mg/300 mg in HDPE bottles containing 30, 90, 100, or 180 tablets with desiccant, induction seal, and non-child-resistant cap when stored (b) (4)

This 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 (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

The listed drug [Tivicay® (dolutegravir)] upon which your application relies is subject to a period of patent and/or exclusivity protection and therefore final approval of your application under

section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

To obtain final approval of this application, submit an amendment two or six months prior to the: 1.) expiration of the patent(s) and/or exclusivity protection or 2.) 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. You should join the antiretroviral pregnancy registry at that time and make the appropriate labeling change that references the existence of the pregnancy registry. 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 deemed approved.

Please note that this drug product may not be marketed in the United States without final agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under Section 501 of the Act and 21 U.S.C. 331(d).

### **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 titled, “Contents of a Complete Submission for the Evaluation of Proprietary Names”, at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022”.)

### **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, please call David Araojo, Pharm.D., Sr. Program Consultant, at (301) 796-0669 or via email at [david.araojo@fda.hhs.gov](mailto:david.araojo@fda.hhs.gov).

Sincerely yours,

*{See appended electronic signature page}*

Jeffrey S. Murray, M.D., M.P.H.  
Deputy Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE(S):

Content of Labeling  
Prescribing Information  
Patient Package Insert  
Container Labeling

55 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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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.**  
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/s/  
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SARITA D BOYD on behalf of JEFFREY S MURRAY  
03/25/2019 09:49:20 AM