DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205493

TENTATIVE APPROVAL

Micro Labs USA Inc.
U.S. Agent for Micro Labs Limited, India
Attention: Kumara Sekar, Ph.D.
Vice President and Head Regulatory Affairs
106 Allen Road, Suite 102
Basking Ridge, NJ 07920

Dear Dr. Sekar:

Please refer to your New Drug Application (NDA) dated May 30, 2013, received June 3, 2013, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for the following drug product:

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

We acknowledge receipt of your amendments dated April 8, 2014, February 2, 2016, and August 24, 2017, which constituted complete responses to our April 3, 2014, October 8, 2014, and July 27, 2016, action letters, respectively.

This NDA provides for the use of Lamivudine and Tenofovir Disoproxil Fumarate Tablets for the treatment of HIV-1 infection in combination with other antiretroviral agents in adults and pediatric patients 12 years of age and older or 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. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the package insert and patient information submitted on January 24, 2018, and immediate container labels submitted on October 1, 2013) and with the minor editorial revisions listed below. Based on the data provided, the expiration dating period is 24 months for Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg in HDPE bottles containing 30 or 100 tablets with induction seal, desiccant, cotton coil, and child-resistant cap when stored below 30ºC (86ºF).

Minor Editorial Revisions for the Package Insert

- Replace "are" with "is" in the INDICATION AND USAGE in the HIGHLIGHTS
- Replace "are" with "is" in the DOSAGE AND ADMINISTRATION section (2.2 and 2.3) in the FULL PRESCRIBING INFORMATON

- Replace “and” with “that” in the DOSAGE AND ADMINISTRATION section (2.3) in the FULL PRESCRIBING INFORMATON

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 drugs [Epivir (lamivudine) and Viread (tenofovir disoproxil fumarate)] upon which your application relies are 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. 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 <u>not</u> 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).

We remind you that if you intend to market this product in the United States after the period of patent and exclusivity protection expires, final approval of your application will require that you comply with all applicable U.S. legislation, including the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), which requires that all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration contain a pediatric assessment unless this requirement is waived, deferred, or inapplicable. A pediatric assessment contains data gathered from pediatric studies using appropriate formulations for each age group for which the assessment is required, and other data that are adequate to: 1.) assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and 2.) support dosing and administration for each pediatric subpopulation for which the product has been assessed to be safe and effective. You must also join the

antiretroviral pregnancy registry at that time and make the appropriate labeling change that references the existence of the pregnancy registry.

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 Monica Zeballos, Pharm.D., Program Coordinator, at (301) 796-0840 or via email at monica.zeballos@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
Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JEFFREY S MURRAY
01/25/2018