

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

205626Orig1s000

Trade Name: Lamivudine, Nevirapine and Zidovudine Tablets, 150 mg/200 mg/300 mg.

Generic or Established: Lamivudine, Nevirapine and Zidovudine Tablets

Sponsor: Micro Labs USA, Inc.

Approval Date: August 13, 2018

Indication: Provides for the use of Lamivudine, Nevirapine and Zidovudine Tablets, 150 mg/200 mg/300 mg alone as a complete regimen or in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg.

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APPROVAL LETTER



NDA 205626

NDA APPROVAL

Micro Labs USA Inc.
U.S. Agent for Micro Labs Limited, India
Attention: Mr. Umesh K Jayakumar, Associate Vice President
106 Allen Road, Suite 102
Basking Ridge, NJ 07920

Dear Mr. Jayakumar:

Please refer to your New Drug Application (NDA) dated and received August 23, 2013, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Lamivudine, Nevirapine and Zidovudine Tablets, 150 mg/200 mg/300 mg.

We acknowledge receipt of your amendments dated July 2, 2014, February 12, 2016, and October 12, 2017, which constituted complete responses to our June 23, 2014, December 31, 2014, and April 20, 2016, action letters, respectively.

We acknowledge receipt of your major amendment dated December 4, 2017, which extended the goal date by three months.

This new drug application provides for the use of Lamivudine, Nevirapine and Zidovudine Tablets, 150 mg/200 mg/300 mg alone as a complete regimen or in combination with other antiretroviral agents for the treatment of 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 approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text. Based on the data provided, the current expiration dating period is 24 months for Lamivudine, Nevirapine and Zidovudine Tablets, 150 mg/200 mg/300 mg in HDPE bottles containing 60 tablets with induction seal and child-resistant cap when stored below 30°C (86°F).

We remind you that in your letters dated April 4, 2018 and April 14, 2018, you stated that you will not be marketing this product in the United States.

WAIVER OF HIGHLIGHTS SECTION

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the prescribing information, text for the Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>

The SPL will be accessible via publicly available labeling repositories.

IMMEDIATE CONTAINER LABELS

Submit final printed immediate container label that is identical to the enclosed immediate container label as soon as it is available, but no more than 30 days after it is printed. Please submit this label electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Container Label for approved NDA 205626.**” Approval of this submission by FDA is not required before the labeling is used.

Please submit one market package of the drug product when it is available to the following address:

Monica Zeballos
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6330
10903 New Hampshire Avenue
Silver Spring, Maryland
Use zip code **20903** if shipping via United States Postal Service (USPS).
Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labels 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm075068.pdf> and “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2008 through 2012”.)

REQUIRED PEDIATRIC ASSESSMENTS

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

We are waiving the pediatric study requirement for patients less than 35 kg because the product does not represent a meaningful therapeutic benefit over existing therapies and is unlikely to be used in a substantial number of patients.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the prescribing information, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the prescribing information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>. Information and Instructions for completing the form can be found at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription

Drug Promotion (OPDP),
see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Monica Zeballos, Pharm.D., Program Coordinator, at (301) 796-0840.

Sincerely yours,

{See appended electronic signature page}

Jeffrey 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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JEFFREY S MURRAY
08/13/2018