

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

200732Orig1s000

Trade Name: Zidovudine Tablets, 100 mg.

Generic Name: Zidovudine

Sponsor: Matrix Laboratories Limited

Approval Date: February 23, 2011

Indications: Provides for the use of Zidovudine Tablets, 100 mg in combination with other antiretrovirals for the treatment of HIV-1 infection.

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CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Other Action Letters	
Labeling	X
REMS	
Summary Review	X
Officer/Employee List	X
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	X
Other Reviews	X
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	X

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APPROVAL LETTER



NDA 200-732

NDA APPROVAL

Matrix Laboratories Limited
Attention: Nitin Bhattad, Regulatory Affairs
1-1-151/1, 4th Floor
Sairam Towers, Alexander Road
Secunderabad-500 003
Andhra Pradesh (AP)
India

Dear Mr. Bhattad:

Please refer to your New Drug Application (NDA) dated April 22, 2010, received April 23, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zidovudine Tablets, 100 mg.

We acknowledge receipt of your amendments dated:

June 29, 2010	January 11, 2011
September 27, 2010 (2)	January 21, 2011

This new drug application provides for the use of Zidovudine Tablets, 100 mg in combination with other antiretrovirals for the treatment of HIV-1 infection.

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 (refer to the enclosed text for the package insert, immediate container, carton, and bulk package label). Also, refer to your original submission for the immediate container label, your September 27, 2010 submission for the carton label, and the agreed-upon labeling emailed on January 31, 2011, for the package insert. Based on the data provided, the expiration dating period is 24 months for Zidovudine Tablets, 100 mg in an HDPE container of 60 tablets with an induction seal and screw cap, (b) (4) when stored at 25°C (77°F), excursions permitted to 15° to 30°C (59° to 86°F).

We remind you of your January 18, 2010, user fee waiver request letter to the Office of Regulatory Policy in which you commit NOT to market Zidovudine Tablets, 100 mg, in the United States.

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 package insert). Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 200-732.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). If the product is to be distributed in developing countries, a system of collecting and reporting adverse drug reactions by the distributor would be desirable (e.g., through governmental or non-governmental agencies).

If you have any questions, call David Araujo, Pharm.D., Senior Program Consultant, at (301) 796-0669.

Sincerely,

{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

ENCLOSURES:

Content of Labeling
Carton, Container, and Bulk 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
02/23/2011