

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-294

APPROVAL LETTER



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-294

NDA APPROVAL

Aurobindo Pharma Limited
Attention: Roopak Sawhney, Regulatory Affairs
Unit III, Survey No. 313 & 314
Bachupally, Quthubullapur Mandal
Hyderabad, Andhra Pradesh-500 072
India

Dear Mr. Sawhney:

Please refer to your new drug application (NDA) 22-294 dated October 3, 2008, received October 7, 2008, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zidovudine Tablets, 60 mg.

We acknowledge receipt of your submissions dated:

December 18, 2007	April 21, 2008	September 4, 2008	July 10, 2009
February 15, 2008	June 2, 2008	December 2, 2008	
March 11, 2008	June 25, 2008	December 12, 2008	
March 17, 2008	August 22, 2008	April 3, 2009	

This new drug application provides for the use of Zidovudine Tablets, 60 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 completed our review of this application. 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, and bulk pack labels). Also refer to your original submission dated December 18, 2007, for the immediate container and bulk pack labels and to the agreed-upon labeling emailed on July 9, 2009 and July 22, 2009, for the package insert. Based on the data provided, the expiration dating period is 24 months for Zidovudine Tablets, 60 mg in ~~—~~ containers of 60 and 1000 tablets and ~~—~~ Aluminum blister packs of 10 when stored at 20° to 25°C (68 to 77°F). ~~—~~ bags of ~~—~~ tablets for bulk shipment (for repacking within 6 months) are also included in this action.

b(4)

We remind you that in your letter dated December 1, 2007, submitted to the Office of Regulatory Policy in support of the user fee waiver request, you committed not to market this product in the United States.

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, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "**SPL for approved NDA 22-294.**"

CARTON AND IMMEDIATE CONTAINER LABELS

Please 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 (October 2005)*.

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 22-294.**" 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.

Please submit one market package of the drug product when it is available.

REPORTING REQUIREMENTS

We remind you that you are expected to comply with the reporting requirements provided in 21 CFR 314.80 and 314.81. If the combination 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 product).

If you have any questions, please call Monica Zeballos, Pharm.D., Senior Program Consultant, at (301) 796-0840 or via email at monica.zeballos@fda.hhs.gov.

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: Draft package insert, immediate container, and bulk pack labels.

Emailed CC: Blessy Johns, U.S. Agent for Aurobindo
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