CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022344Orig1s000

OTHER ACTION LETTERS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-344

TENTATIVE 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) 22-344 dated and received March 9, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg.

We acknowledge receipt of your submissions dated:

January 11, 2010	August 19, 2010	January 4, 2011
March 11, 2010	August 25, 2010	
June 2, 2010	November 27, 2010	

This NDA provides for the use of Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg in combination with other antiretrovirals for the treatment of HIV-1 infection in adults and pediatric patients 12 years old and older.

This NDA was reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR).

We completed our review of this application. It is **tentatively approved** under 21 CFR 314.105 for use as recommended in the agreed-upon labeling (refer to the enclosed text for the package insert, patient information, and immediate container, carton and bulk pack labels). Also refer to the agreed-upon labeling emailed on January 7, 2011, for the package insert and patient information. Based on the data provided, the expiration dating period is 24 months for Lamivudine and Tenofovir Disoproxil Fumarate Tablets, 300 mg/300 mg in a HDPE container of 30 tablets with an induction seal, desiccant, and child-resistant ca (b) (4)

The tentative approval is predicated upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the

facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.
The listed reference drug products [Epivir® (lamivudine) and Viread® (tenofovir disoproxil fumarate)] upon which you base your application are subject to a period of patent 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. If you have questions as to when this date will be, please contact the Agency at the information provided below.

Two or six months prior to the expiration of the patents protection, as appropriate, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. Any changes to the conditions outlined in this NDA require our review before final approval and the goal date for our review will be set accordingly. Your amendment should include updated labeling, chemistry, manufacturing and controls data, and a safety update. This amendment should include draft final printed labels and labeling which comply with all United States regulations (uniqueness of drug product appearance per 21 CFR 206; child-resistant packaging per 16 CFR 1700, etc.). This amendment should be designated clearly in your cover letter as a "**FINAL APPROVAL REQUESTED**."

Failure to submit this amendment will prompt a review of this application that may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

We 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).

We remind you that, should you intend to market this product in the United States after the period of patent protection, you are required to join the antiretroviral pregnancy registry at that time and make the appropriate labeling change that references the existence of the pregnancy registry. In addition, an updated package insert (PI) must be submitted under the Structured Product Labeling requirements (http://www.fda.gov/oc/datacouncil/spl.html) as defined by the Physician's Labeling Rule [21 CFR 201.56, 201.57].

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before the period of patent protection has expired, you should amend your application accordingly.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed in the United States before final approval.

If you have any questions, please contact Monica Zeballos, Pharm.D., Senior Program Consultant, at (301) 796-0669 or 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

Enclosures: Draft PI, patient information, immediate container, carton, and bulk pack labels

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

45 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 and this page is the manifestation of the electronic signature.

/s/

JEFFREY S MURRAY
01/07/2011