DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-294/S-002

SUPPLEMENT 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. Sawhey:

Please refer to your Supplemental New Drug Application (sNDA) dated June 29, 2010, received June 30, 2010, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zidovudine Tablets, 60 mg.

We acknowledge receipt of your amendment dated November 9, 2010.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

- Addition of an alternate manufacturing site (Aurobindo Pharma Limited Unit VII)
- Addition of an alternate analytical testing site
- Addition of an alternate packaging and labeling site (immediate container labels of 60 (b) (4)
- Expansion of pediatric dosing guidelines from ≥6 weeks to ≥4 weeks < 18 years of age for Retrovir® (zidovudine) Syrup, Capsules and Tablets
- To update the "Patient Counseling" section with information related to HIV-1/HCV co-infection, lactic acidosis/hepatomegaly, and myopathy
- Addition of Biaxin (clarithromycin) data to Table 9: Effect of Coadministered Drugs on Zidovudine AUC in section 12.3 Pharmacokinetics

We completed our review of this supplemental new drug application under the President's Emergency Plan for AIDS Relief (PEPFAR). It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements and any annual reportable changes not included in the enclosed labeling. 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

CARTON AND IMMEDIATE CONTAINER LABELS

Please submit final printed container and bulk pack labels that are identical to the enclosed immediate container and bulk pack 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 "**Product Correspondence – Final Printed Container and Bulk Pack Labels for approved NDA 22-294S-002**." Approval of this submission by FDA is not required before the labeling is used.

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, please call Monica Zeballos, Pharm.D., Senior Program Consultant, 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
Food and Drug Administration

ENCLOSURES: Content of Labeling, Container and Bulk Pack Labeling

Email CC: Blessy Johns, U.S. Agent for Aurobindo Pharma Limited
2400 Route 130 North
Dayton, NJ 08810

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
12/30/2010