DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-939

Aurobindo Pharma Ltd
ATTN: Mr. G. Srinivas, M. Pharm
Principal Scientist
Plot No. 2 Maitrivihar,
Ameerpet, Hyderbad-500 038
India

Dear Mr. G. Srinivas:

Please refer to your new drug application 21-939 dated, January 4, 2006 received on January 11, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine 150mg/Zidovudine 300mg/Nevirapine 200mg Tablets.

We acknowledge receipt of your submissions dated:

November 19, 2006	April 18, 2006
January 4, 2006	May 15, 2006
February 9, 2006	June 30, 2006

This NDA provides for the use of Lamivudine 150mg/Zidovudine 300mg/Nevirapine 200mg Tablets for the treatment of HIV-1 infection.

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 and medication guide). Also refer to your submission emailed to the Agency on June 30, 2006 and to the agreed upon label emailed on June 30, 2006 for the immediate container and carton labels**.** The tentative approval is contingent 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 upon which you base your application are subject to a period of patent protection and therefore, final approval of your application under section 505(b) 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.

At least 180 days prior to the expiration of patent protection or when requested, submit an amendment to this application identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in rescission of the tentative approval letter.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

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 products).

We remind you that, should you intend to market this product in the U.S. 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. You should also amend your application with a container label that is compliant with the Poison Prevention Packaging Act as it applies to child resistant packaging.

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 U.S. before final approval.

If you have any questions, call Vasavi Reddy, RPh, MPH, Sr Program Management Officer at (301) 796-0793 or via email at vasavi.reddy@fda.hhs.gov

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Attachments: PI, Immediate container & carton label

CC:
Prasada Reddy Kambham
U.S. Agent

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jeffrey Murray

6/30/2006 12:39:27 PM