



NDA 21-943

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

Dear Mr G Srinivas:

Please refer to your new drug application 21-943 dated December 28, 2005, received on December 28, 2005, submitted as a rolling review application pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine 150mg/Zidovudine 300mg Fixed- Dose Tablets co-packaged with Efavirenz 600mg Tablets.

We acknowledge receipt of your submissions dated:

September 28, 2005 February 17, 2006
October 11, 2005 February 21, 2006
December 28, 2005 February 22, 2006

This NDA provides for the use of Lamivudine 150mg/Zidovudine 300mg Fixed-Dose Tablets co-packaged with Efavirenz 600mg 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 patient package insert). Also refer to your submission dated February 24, 2006 and to the agreed upon labeling as documented in your submission dated February 6, 2006 for the immediate container and carton labels. This determination 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 product upon which you base your application is subject to a period of patent and exclusivity 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 us at the information provided below.

At least 180 days prior to the expiration of patent and exclusivity 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., you are required to join the antiretroviral pregnancy registry at that time and make the appropriate label changes that references the existence of the pregnancy registry and amend your application with container labeling 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 and exclusivity 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 Consultant 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

CC:
G Srinivas, M. Pharm
Principal Scientist
Plot No. 2 Maitrivihar,
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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 Murray
3/6/2006 11:17:53 AM