



NDA 21-969

Cipla Limited
ATTN: Ms Vaishali Shridhankar
Regulatory Affairs
289, Bellasis Rd
Mumbai Central
Mumbai 400083

Dear Ms Shridhankar:

Please refer to your new drug application (NDA) 21-969 submitted under rolling review with the final major submission dated, May 18, 2006 received on May 19, 2006, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine 150mg/Stavudine 30mg /Nevirapine 200mg Tablets and Lamivudine 150mg/Stavudine 40mg/Nevirapine 200mg Tablets.

We acknowledge receipt of your submissions dated:

February 16, 2006	May 18, 2006
March 20, 2006	August 31, 2006
April 20, 2006	October 12, 2006

This NDA provides for the use of Lamivudine 150mg/Stavudine 30mg /Nevirapine 200mg Tablets and Lamivudine 150mg/Stavudine 40mg/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 in **addition to the changes outlined below** (refer to the enclosed text for the package insert and medication guide). Also refer to your submission emailed to the Agency on November 17, 2006 and to the agreed upon label dated February 16, 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.

Additional changes to package insert and medguide:

- **Package insert:**

- Under Dosage and Administration for adults and pediatric patients, dosage recommendations based on weight have been revised. Please refer to attached label for new recommendations.

- **Medguide:** The following sections were revised to be consistent with revised attached labeling;
 - What is the most important information I should know about LAMIVUDINE, STAVUDINE AND NEVIRAPINE TABLETS?
 - How should I take LAMIVUDINE, STAVUDINE AND NEVIRAPINE TABLETS?

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 a “**MINOR AMENDMENT – FINAL APPROVAL REQUESTED**”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 control 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 submitted even if none of these changes were made. This amendment should be designated clearly in your cover letter as a “**MINOR AMENDMENT – FINAL APPROVAL REQUESTED**”.

Failure to submit this amendment will prompt a review of the 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.

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. 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 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: revised PI & medguide, Immediate container & carton label

CC:

(b)(4)

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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
11/17/2006 04:42:52 PM