



NDA 200-244

TENTATIVE APPROVAL

Hetero Drugs Limited Unit III
Attention: P. Khadgpathi, Director Pharma
22-110, Industrial Development Area
Jeedimetla, Hyderabad-500 055
India

Dear Dr. Khadgpathi:

Please refer to your new drug application (NDA) 200-244 dated August 21, 2009, received on August 27, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine, Nevirapine, and Stavudine Tablets, 150 mg/200 mg/30 mg. This application was considered complete for review based on the receipt date of your November 9, 2009 submission.

We acknowledge receipt of your submissions dated:

September 29, 2009
November 9, 2009
February 2, 2010

July 20, 2010
August 11, 2010
August 13, 2010

August 31, 2010

This NDA provides for the use of Lamivudine, Nevirapine, and Stavudine Tablets, 150 mg/200 mg/30 mg alone as a complete regimen or in combination with other antiretrovirals for the treatment of HIV-1 infection.

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

We completed our review of this application, as amended. 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, medication guide, and immediate carton and container labels). Also, refer to your August 31, 2010 submission for the immediate carton and container labels and the agreed-upon labeling emailed on September 8, 2010, for the package insert and patient medication guide. Based on the data provided, the expiration dating period is 24 months for Lamivudine, Nevirapine, and Stavudine Tablets, 150 mg/200 mg/30 mg in HDPE containers of 60 tablets, 100 tablets, and 500 tablets when stored at 20° to 25°C (68° to 77°F).

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.

Two of the listed reference drug products [Epivir[®] (lamivudine) and Viramune[®] (nevirapine)] 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 patent's 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 patents 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 expiration of the patents protection, 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 David Araujo, Pharm.D., Senior Program Consultant, at (301) 796-0669 or by email at david.araujo@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: PI, MedGuide, immediate carton and container labels

Email CC: Dr. Sudhakar Vidiyala, InvaGen Pharmaceuticals, Inc.
U.S. Agent for Hetero Drugs Limited Unit III

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-200244	ORIG-1	HETERO DRUGS LTD UNIT III	Lamivudine/Nevirapine/Stavudine FDC Tabs (150mg/200mg/30mg)

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
09/10/2010