DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-356

Hetero Drugs Limited Unit III
Attention: G. Sangeetha, Regulatory Affairs
22-110, Industrial Development Area
Jeedimetla, Hyderabad-500 055
India

Dear Mr. G. Sangeetha:

Please refer to your new drug application (NDA) 22-356 dated and received on July 7, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Lamivudine/Zidovudine Tablets, 150 mg/300 mg Co-packaged with Nevirapine Tablets, 200 mg.

The July 7, 2008, submission constituted a response to our March 14, 2008, unacceptable-for-filing letter issued because the user fee requirement was not met in your original NDA submission dated February 18, 2008. Subsequently, the user fee waiver was granted.

We acknowledge receipt of your submissions dated:

February 18, 2008	July 10, 2009	March 23, 2009
July 8, 2008	August 11, 2008	April 6, 2009

This NDA provides for the use of Lamivudine/Zidovudine Tablets, 150 mg/300 mg Co-packaged with Nevirapine Tablets, 200 mg for use 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. 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 bulk pack labels). Also refer to your original submission for the bulk pack labels and to the agreed-upon labeling emailed on May 7, 2009, for the package insert and medication guide. Based on the data provided, the expiration dating period is 24 months for Lamivudine/Zidovudine Tablets, 150 mg/300 mg Co-packaged with Nevirapine Tablets, 200 mg in PVC/Alu and PVC/PVDC blister packs with 10 doses on one blister sheet and 6 sheets included in the carton when stored at 20º-25ºC (68º to 77ºF).

The tentative approval is predicated 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, please submit a "**MINOR AMENDMENT – FINAL APPROVAL REQUESTED**" as 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 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.

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 co-packaged 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 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 United States before final approval.

If you have any questions, please contact Monica Zeballos, Pharm.D., Senior Program Consultant, at (301) 796-0669 or by email at monica.zeballos@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

Attachments: Draft PI, medication guide, and bulk pack labels

Emailed CC: Dr. Sudhakar Rao Vidiyala, U.S. Agent for Hetero Drugs Limited Unit III
Ravi Kumar Vatchavai, U.S. Regulatory Agent for Hetero Drugs Limited Unit III
InvaGen Pharmaceuticals Inc.
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Hauppauge, NY 11788

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

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