



ANDA 78-957

InvaGen Pharmaceutical Inc.  
U.S. Agent for: Hetero Drugs Limited, Unit III  
Attention: Sudhakar Rao Vidiyala, Ph.D.  
President  
7 Oser Avenue  
Hauppauge, NY 11788

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Stavudine Capsules USP, 15 mg, 20 mg, 30 mg, and 40 mg.

Reference is also made to your amendments dated July 10, July 20, September 3, and December 3, 2007; and January 25, 2008.

This ANDA was reviewed under the expedited review provisions of the President's Emergency Plan for AIDS Relief (PEPFAR).

We have completed the review of this ANDA, and we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug (RLD) upon which you have based your ANDA, Zerit® Capsules, 15 mg, 20 mg, 30 mg, and 40 mg of Bristol Myers Squibb Company Pharmaceutical Research Institute, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S.

Patent No. 4,978,655 (the '655 patent), is scheduled to expire on December 24, 2008 (with pediatric exclusivity extension). Your ANDA contains a paragraph III certification to the '655 patent under section 505(j)(2)(A)(vii)(III) of the Act stating that Hetero Drugs Limited, Unit III will not market Stavudine Capsules USP, 15 mg, 20 mg, 30 mg, and 40 mg in the United States under this ANDA prior to the expiration of this patent. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until the '655 patent has expired, currently, December 24, 2008.

We also note your commitment to have an Antiretroviral Pregnancy Registry in place prior to this ANDA receiving full approval.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed in the United States without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book." Should you believe that there are grounds for issuing the final approval letter prior to December 24, 2008, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Laura Longstaff, Project Manager, at 240-276-8500.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research