DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 201107

Hetero USA, Inc.
U.S. Agent for: Hetero Labs Limited, Unit-III
Attention: Soma Raju, Ph.D.
Director, Regulatory Affairs
1035 Centennial Avenue
Piscataway, NJ 08854

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 11, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Abacavir Oral Solution USP, 20 mg/mL.

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

Reference is also made to your amendments dated November 2, and November 18, 2010; February 1, and July 26, 2011; and April 4, June 25, June 27, and June 28, 2012.

We have completed the review of this ANDA, and based upon the information you have presented to date 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 patents and exclusivity 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 practice (cGMP) 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, Ziagen Oral Solution, 20 mg/mL of VIIV Healthcare (VIIV), is subject to periods of patent protection. The following unexpired patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products

with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

| U.S. Patent Number | Expiration Date |
|---|---|
| 6,294,540 (the '540 patent) | November 14, 2018* |
| 6,641,843 (the '842 patent) | August 4, 2019* |

*with pediatric exclusivity added

Your ANDA contains paragraph III certifications to each of these patents under section 505(j)(2)(A)(vii)(III) of the Act stating that Hetero Drugs Limited, Unit-III will not market Abacavir Oral Solution USP, 20 mg/mL, in the U.S. prior to the expiration of each of these patents and their associated exclusivity. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until each of these patents and exclusivity have expired, currently, August 4, 2019.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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 cGMPs are subject to agency review before final approval of the ANDA 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 U.S. 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 August 4, 2019, 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 Sean Belouin, Project Manager, at 240-276-8555.

Sincerely yours,

*{See appended electronic signature page}*

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

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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.**

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/s/

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ROBERT L WEST

07/02/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.