



ANDA 091677

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 July 10, 2009 submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lopinavir and Ritonavir Tablets, 200 mg/50 mg.

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 July 24, August 24, October 23, November 3, and November 25, 2009; March 1, March 25, June 1, June 2, July 1, and November 9, 2010; February 16, July 18, and August 17, 2011; February 23, April 20, May 4, and May 16, 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 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 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, Kaletra® Tablets, 200 mg/50 mg, of Abbott Laboratories, is subject to periods of patent protection. The following patents

with 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>U.S. Patent Number</u>	<u>Expiration Date</u>
5,541,206 (the '206 patent)	January 30, 2014*
5,648,497 (the '497 patent)	January 15, 2015*
5,886,036 (the '036 patent)	May 19, 2014*
5,914,332 (the '332 patent)	June 13, 2016*
6,037,157 (the '157 patent)	December 26, 2016*
6,284,767 (the '767 patent)	August 15, 2016*
6,703,403 (the '403 patent)	December 26, 2016*
7,148,359 (the '359 patent)	January 19, 2020*
7,364,752 (the '752 patent)	May 10, 2021*
8,025,899 (the '899 patent)	March 26, 2028*

*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 Labs Limited Unit III will not market Lopinavir and Ritonavir Tablets, 200 mg/50 mg in the U.S. prior to the expiration of the patents. 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 has expired, currently, March 26, 2028.

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 March 26, 2028, 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 Linda Park, Project Manager, at 240-276-8536.

Sincerely yours,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

05/23/2012

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