DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091203

Byron Chemical Co. Inc.
U.S. Agent for: Cipla Limited
Attention: Vaishali Shidhankar
Regulatory Affairs
40/11 23rd Street
Long Island City, NY 11101

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated July 7, 2009 submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lopinavir and Ritonavir Oral Solution, 80 mg/20 mg per 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 August 3, and August 11, 2009; April 22, June 15, September 7, and November 11, 2010; March 1, July 12, August 16, and December 23, 2011; and February 14, March 1, and June 27, 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 and exclusivity issues 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 manufacturing 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® Oral Solution (Lopinavir and Ritonavir Oral Solution), 80 mg/20 mg per mL of Abbott Laboratories, is subject

to periods of patent and exclusivity 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.S. Patent Number	Expiration Date
5,484,801 (the '801 patent)	July 28, 2014*
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*
5,948,436 (the '436 patent)	March 13, 2014
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*
6,911,214 (the '214 patent)	May 28, 2022

*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 Cipla Limited will not market Lopinavir and Ritonavir Oral Solution, 80 mg/20 mg per mL in the U.S. prior to the expiration of each of these patents. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until all these patents have expired, currently, May 28, 2022.

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 May 28, 2022, 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

06/29/2012

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