CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 091338

TENTATIVE APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091338

Torrent Pharma Inc.
U.S. Agent for : Torrent Pharmaceuticals Limited
Attention: Dawn M. Chitty
Vice President of Regulatory Affairs
5380 Holiday Terrace, Suite 40
Kalamazoo, MI 49009

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated February 13, 2009 submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Levetiracetam Extended Release Tablets, 500 mg and 750 mg (Once a Day Dosage).

Reference is also made to your amendments dated February 24, April 13, May 26, and September 20, 2010.

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. The reference listed drug (RLD) upon which you have based your ANDA, Keppra XR Tablets, 500 mg and 750 mg of UCB Inc., is subject to a period of market exclusivity. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), the New Dosage Form (NDF) exclusivity awarded to Keppra XR Tablets is scheduled to expire on September 12, 2011. It is for this reason that your ANDA is **tentatively approved**. This tentative approval action 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 action is subject to change on the basis of new information that may come to our attention.

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, if 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 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 September 12, 2011, 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 Bob Gaines, Project Manager, at 240-276-8495.

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

11/17/2010

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