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APPLICATION NUMBER:

ANDA 091093

TENTATIVE APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091093

Watson Laboratories, Inc. - Florida
Attention: Janet Vaughn
Director, Regulatory Affairs
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated January 14, 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.

Reference is made to your amendments dated May 28, July 8, and August 10, 2009; February 17, March 2, May 6, May 14 and December 3, 2010; and February 16, February 25, May 26, June 22, and June 29, 2011.

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 exclusivity 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. This letter does not address issues related to 180-day generic drug exclusivity.

The reference listed drug (RLD) upon which you have based your ANDA, Keppra XR Tablets, of UCB, Inc., 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. 7,858,122 (the '122 patent), is scheduled to expire on September 17, 2028.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '122 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Levetiracetam Extended-Release Tablets, 500 mg and 750 mg, under this ANDA. You have notified the agency that Watson laboratories, Inc. – Florida (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Watson.

Because of the new dosage form exclusivity held by the RLD, we are unable at this time to grant final approval to your ANDA. This exclusivity will expire on September 12, 2011.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT – FINAL APPROVAL REQUESTED" upon receipt of this tentative approval letter. 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 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 to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Steven Yang, Project Manager, at (240) 276-8476.

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

07/14/2011

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