DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 200828

Watson Laboratories, Inc.
Attention: Krishna Joshi
Manager, Regulatory Affairs
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on December 21, 2009, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg.

Reference is also made to your amendments dated July 12, and November 1, 2010; April 4, and April 14, 2011; April 2, May 23, September 10, October 9, and December 12, 2012; and January 14, and May 7, 2013.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Lamictal ODT 25 mg, 50 mg, 100 mg and 200 mg, respectively, of GlaxoSmithKline LLC (GSK). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, GSK's Lamictal ODT, 25 mg, 50 mg, 100 mg, and 200 mg, 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. 7,919,115 (the '115 patent) is scheduled to expire on January 4, 2029.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '115 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg, under this ANDA. You have notified the agency that Watson Laboratories, Inc. (Watson) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Watson.

With respect to 180-day generic drug exclusivity, we note that Watson was the first ANDA applicant for Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg, to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, Watson may be eligible for 180 days of generic drug exclusivity for Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). The agency notes that Watson failed to obtain tentative approval of this ANDA within 40 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failed to obtain tentative approval).[1] The agency is not, however, making a formal determination at this time of Watson's eligibility for 180-day generic drug exclusivity. It will do so only if another paragraph IV applicant becomes eligible for full approval (a) within 180 days after Watson begins commercial marketing of Lamotrigine Orally Disintegrating Tablets, 25 mg, 50 mg, 100 mg, and 200 mg, or (b) at any time prior to the expiration of the listed patents if Watson has not begun commercial marketing. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

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.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

[1] For applications submitted between January 9, 2010, and July 9, 2012, section 1133 of the Food and Drug Administration Safety and Innovation Act (FDASIA) (P.L. 112-144) extends this period to 40 months. This includes applications such as ANDA 200828 "amended during such period to first contain [a PIV certification]…" Watson therefore qualifies for 40 (not 30) months in the application of section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failed to obtain tentative approval). However, this 40-month period dates from the date of receipt of the ANDA (December 21, 2009), not the date the paragraph IV amendment was received.(April 14, 2011), because this ANDA does not meet the terms of section 1133(b) of FDASIA.

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting Director
Office of Generic Drugs
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

07/15/2013

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.