DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 205102

APPROVAL: 500 mg and 1, 000 mg
TENTATIVE APPROVAL: 250 mg and 750 mg

Secan Pharmaceuticals, Inc.
81 Lancaster Ave, #120, Great Valley Center
Malvern, PA 19355
Attention: Yichen Wei
Administrative Manager

Dear Sir or Madam:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Levetiracetam Tablets USP, 250 mg, 500 mg, 750 mg, and 1,000 mg.

Reference also is made to your amendments dated February 11, February 14, April 18, 2014; June 8, August 2, August 6, September 7, November 4, and December 2, 2015. Reference also is made to the letter issued by this office on December 16, 2015, granting approval to your Levetiracetam Tablets USP, 250 mg, 750 mg, and 1,000 mg; and granting tentative approval to your Levetiracetam Tablets USP, 500 mg.

We have determined that the agency erred in approving your ANDA 205102 for Levetiracetam Tablets USP, 250 mg and 750 mg, and granting tentative approval for Levetiracetam Tablets USP, 500 mg. Specifically, we should have approved the 500 mg strength, and tentatively approved the 250 mg and 750 mg strengths. The agency's decision with respect to your Levetiracetam Tablets USP, 1,000 mg is unchanged and that strength remains approved. This amended action letter reflects the appropriate actions for the four strengths in the ANDA. Please note that the effective date of action will remain December 16, 2015, the date of the original letter.

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. The Office of Bioequivalence has determined your Levetiracetam Tablets USP, 250 mg, 500 mg, 750 mg and 1,000 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Keppra Tablets USP, 250 mg, 500 mg, 750 mg and 1,000 mg, of UCB Inc. (UCB). However, we are unable to grant final approval to your Levetiracetam Tablets USP, 250 mg and 750 mg, because of the exclusivity issue noted below. Therefore, your Levetiracetam Tablets USP, 500 mg and 1,000 mg, are approved. The 250 mg and 750 mg strengths are tentatively approved. Your dissolution testing should be incorporated

into the stability and quality control program using the same method proposed in your application.

The RLD upon which you have based your application, UCB's Keppra Tablets USP, 250 mg, 500 mg, 750 mg and 1,000 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. 8,802,142 (the '142 patent) is scheduled to expire on December 7, 2031 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification to the '142 patent[1] under section 505(j)(2)(A)(vii)(IV) of the FD&C Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use or sale of Levetiracetam Tablets USP, 250 mg, 500 mg, 750 mg, and 1,000 mg. You have notified the agency that Secan Pharmaceuticals, Inc. (Secan) complied with the requirements of section 505(j)(2)(B) of the FD&C Act, and that no litigation was brought within the 45-day statutory period.

With respect to 180-day generic drug exclusivity, we note that Secan was the first ANDA applicant for Levetiracetam Tablets USP, 500 mg to submit a substantially complete ANDA with a paragraph IV certification to the '142 patent. Therefore, with this approval, Secan is eligible for 180 days of generic drug exclusivity for Levetiracetam Tablets USP, 500 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the FD&C Act, will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv).[2] Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run. While your Levetiracetam Tablets USP, 1,000 mg product is approved, this strength is not eligible for 180-day exclusivity.

We are unable at this time to grant final approval to your ANDA for Levetiracetam Tablets USP, 250 mg and 750 mg. Prior to the submission of your paragraph IV certification to the '142 patent, another applicant or applicants submitted a substantially complete ANDA providing for Levetiracetam Tablets USP, 250 mg and 750 mg, and containing a paragraph IV certification to the '142 patent. Your ANDA will be eligible for final approval on the date that is 180 days after the commercial marketing date or court decision date identified in section 505(j)(5)(B)(iv) of the FD&C Act, as in place prior to 2003.[3]

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[1] We note that the '142 patent was submitted to the agency after submission of your ANDA. Litigation, if any, with respect to this patent would not create a statutory stay of approval.

[2] Because another ANDA for Levetiracetam Tablets USP, 250 mg, 500 mg, and 750 mg was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provisions is to the section of the FD&C Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1). This means that the period of exclusivity will begin on the earlier of the date of first commercial marketing of your product or the date of the decision of a court holding the '142 patent invalid or not infringed by the drug covered by an ANDA. That decision would need to be "a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken." MMA § 1102(b)(3).

[3] Id. This means that the period of exclusivity will begin on the earlier of the date of first commercial marketing of the other applicant's product or the date of the decision of a court holding the '142 patent invalid or not infringed by the drug covered by an ANDA.

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 FD&C 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(s) directly to:

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,

Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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