DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-794

Kendle Regulatory Affairs/AAC Consulting Group, Inc.
Attention: Anthony Celeste
U.S. Agent for: Sun Pharmaceutical Industries Ltd.
7361 Calhoun Place, Suite 500
Rockville, MD 20855-2765

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated July 8, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxcarbazepine Tablets, 150 mg, 300 mg and 600 mg.

Reference is also made to your amendments dated December 22, 2005; June 1, and November 21, 2006; and March 30, August 16, August 31, September 7, and September 14, 2007.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Oxcarbazepine Tablets, 150 mg, 300 mg and 600 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Trileptal Tablets of Novartis Pharmaceuticals Corp (Novartis). 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, Novartis' Trileptal Tablets, 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. 7,037,525 (the '525 patent), is scheduled to expire on August 12, 2018 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification to the '525 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be

infringed by your manufacture, use, or sale of Oxcarbazepine Tablets, 150 mg, 300 mg and 600 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Sun Pharmaceutical Industries Ltd. (Sun) for infringement of the listed '525 patent. You have notified the agency that Sun complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the ‘525 patent was brought against Sun within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to 180-day generic drug exclusivity, we note that Sun was one of the first ANDA applicants to submit a substantially complete ANDA with a paragraph IV certification to the '525 patent. Therefore, with this approval, Sun is eligible for 180-days of shared generic drug exclusivity for Oxcarbazepine Tablets, 150 mg, 300 mg and 600 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv). Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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.

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications, with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

*{See appended electronic signature page}*

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/
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Robert L. West
10/9/2007 03:04:16 PM
for Gary Buehler