DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077555

Caraco Pharmaceutical Laboratories, Ltd.
U.S. Agent for Sun Pharmaceutical Industries Ltd.
Attention: Robert Kurkiewicz
Vice President, Regulatory Affairs
1150 Elijah McCoy Drive
Detroit, MI 48202

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated February 1, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tiagabine Hydrochloride Tablets, 2 mg and 4 mg.

Reference is made to the tentative approval letter issued by this office on March 15, 2007, and also to your amendments dated July 8, and July 25, 2011.

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 Tiagabine Hydrochloride Tablets, 2 mg and 4 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Gabitril Tablets 2 mg and 4 mg, respectively, of Cephalon, Inc. (Cephalon). 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, Cephalon's Gabitril Tablets 2 mg and 4 mg, is subject to periods of patent protection. The following unexpired patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,354,760 (the '760 patent)	March 24, 2012
5,866,590 (the '590 patent)	April 29, 2016
5,958,951 (the '951 patent)	June 10, 2017

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tiagabine Hydrochloride Tablets, 2 mg and 4 mg, under this ANDA. You have notified the agency that Sun Pharmaceutical Industries Ltd., (Sun) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement 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 the first ANDA applicant to submit a substantially complete ANDA with paragraph IV certifications to the ‘760, ‘590, and ‘951 patents. Therefore, with this approval, Sun is eligible for 180 days of generic drug exclusivity for Tigabine Hydrochloride Tablets, 2 mg and 4 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 the 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:

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.

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/U CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

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

11/04/2011

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