DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-115

Taro Pharmaceuticals U.S.A., Inc.
Attention: Kavita Srivastava
Director, Regulatory Affairs
U.S. Agent for: Taro Pharmaceutical Industries Ltd.
3 Skyline Drive
Hawthorne, NY 10532

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 29, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Carbamazepine Extended-release Tablets USP, 100 mg, 200 mg and 400 mg.

Reference is also made to your amendments dated December 7, 2006; January 4, and January 17, 2007; and January 24, January 25 (2 submissions), March 10, March 13, August 21, October 16, November 12, and November 17, 2008.

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 Carbamazepine Extended-release Tablets USP, 100 mg, 200 mg and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Tegretol-XR Tablets, 100 mg, 200 mg and 400 mg, respectively, of Novartis Pharmaceuticals Corporation (Novartis).

The dissolution testing should be incorporated into your stability and quality control program using the same method proposed in your ANDA. The "interim" dissolution specifications are as follows:

Medium:	Acetate Buffer, pH 4.5, at 37 ^{0}C
Volume:	900 mL

Apparatus:	Apparatus I (Basket) at 100 rpm	
Specifications:	100 mg	200 mg and 400 mg
3 hours	(b) (4)	(b) (4)
6 hours	(b) (4)	(b) (4)
12 hours	NLT (b)	NLT (b)
24 hours	NLT (b)	NLT (b)

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" if there are no revisions to be made to the "interim" specifications or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Novartis' Tegretol-XR Tablets, is subject to a period of unexpired patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 5,284,662 (the '662 patent) is scheduled to expire on February 8, 2011.

Your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '662 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Carbamazepine Extended-release Tablets USP, 100 mg, 200 mg and 400 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 was brought against Taro Pharmaceutical Industries Ltd. (Taro) for infringement of the '662 patent that was the subject of the paragraph IV certification. You have notified the agency that Taro complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '662 patent was brought against Taro within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(2)(B)(iii) of the Act.

With respect to 180-day generic drug exclusivity, we note that Taro was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification for Carbamazepine Extended-release Tablets USP, 100 mg. (Taro was not the first such applicant with respect to the 200 mg and 400 mg strengths.) Therefore, with this approval, Taro may be eligible for 180 days of generic drug exclusivity for

Carbamazepine Extended-release Tablets USP, 100 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). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins. The agency notes that Taro failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) of the Act. However, the agency is not making a formal determination at this time of Taro's eligibility for 180-day generic drug exclusivity. It will do so only if another applicant becomes eligible for approval within 180 days after Taro begins commercial marketing of Carbamazepine Extended-release Tablets USP, 100 mg.

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:

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 78-115".***

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
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
3/31/2009 04:50:02 PM
Deputy Director, for Gary Buehler