DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078974

Hi-Tech Pharmacal Co., Inc.
Attention: Joanne Curri
Director, Regulatory Affairs
369 Bayview Avenue
Amityville, NY 11701

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 27, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Gabapentin Oral Solution, 250 mg/5 mL.

Reference is also made to your amendments dated November 3, 2008; May 27, 2009; February 5, May 28, June 9, and December 14, 2010; and February 2, and February 8, 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 Gabapentin Oral Solution, 250 mg/5 mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Neurontin of Parke Davis.

The RLD upon which you have based your ANDA, Neurontin Oral Solution, 250 mg/5 mL, of Parke Davis is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 6,054,482 (the '482 patent) and 7,256,216 (the '216 patent) are scheduled to expire (with pediatric exclusivity added) on October 25, 2017, and November 28, 2022, respectively.

With respect to both patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale Gabapentin Oral Solution, 250 mg/5 mL, under this ANDA. You notified the agency that Hi-Tech Pharmacal Co., Inc. (Hi-Tech) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Hi-Tech 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 Hi-Tech was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '216

patent. Therefore, with this approval, Hi-Tech is eligible for 180 days of generic drug exclusivity for Gabapentin Oral Solution, 250 mg/5 mL. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act,[1] will begin to run from the earlier of the commercial marketing or court decision dates 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.

Post marketing 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.

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

[1] Because another ANDA containing a paragraph IV certification to the '482 patent 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 provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

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

02/18/2011

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