DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 77-428

Food and Drug Administration
Rockville MD 20857

JUN 21 2006

King and Spalding
Attention: Christina Markus
U.S. Agent for: Genpharm Inc.
1730 Pennsylvania Avenue N.W.
Washington, DC 20006-4706

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 7, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lamotrigine Tablets, 25 mg, 100 mg, 150 mg and 200 mg.

Reference is also made to your amendments dated July 26, and September 29, 2005; and February 17, March 16, April 21, and May 31, 2006.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the presence of the patent noted below. Therefore, the ANDA is **tentatively approved.** This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention.

The referenced listed drug (RLD) upon which you have based your ANDA, Lamictal Tablets, 25 mg, 100 mg, 150 mg and 200 mg, of GlaxoSmithKline, is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations the "Orange Book", U.S. Patent 4,602,017 (the '017 patent) is scheduled to expire on July 22, 2008. Your application contains a paragraph III patent certification to the '017 patent under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not

market this drug product prior to the expiration of this patent. Therefore, final approval of your application may not be made effective pursuant to 21 USC 355(j)(5)(B)(ii) of the Act until the '017 patent has expired; i.e., July 22, 2008.

In order to reactivate your application prior to final approval, please submit a MINOR AMENDMENT - FINAL APPROVAL REQUESTED 90 days prior to the date you believe that it will be eligible for final approval. This amendment should provide a statement of the reasons you believe the ANDA is eligible for final approval, and it should also identify changes, if any, in the conditions under which the product was tentatively approved; i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the ANDA will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book." Should you believe that there are grounds for issuing the final approval letter prior to July 22, 2008, you should amend your ANDA accordingly.

For further information on the status of this ANDA or upon submitting an amendment to the ANDA, please contact Lisa Kwok, Project Manager, at 301-827-9275.

Sincerely yours,

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