DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-388

AUG 30 2006

TEVA Pharmaceuticals USA
Attention: Philip Erickson, R.Ph.
Senior Director, Regulatory Affairs
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated April 1, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Lamotrigine Tablets, 25 mg, 100 mg, 150 mg, and 200 mg.

Reference is made to your amendments dated November 19, 2004; November 22, 2005; and February 10, March 17, March 28, April 11, May 23, and August 1, 2006. We also acknowledge receipt of your correspondence dated August 20, 2002, and April 20, 2005, pertaining to the patent issues associated with this ANDA.

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 Lamotrigine Tablets, 25 mg, 100 mg, 150 mg, and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Lamictal Tablets, 25 mg, 100 mg, 150 mg, and 200 mg, respectively, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The referenced listed drug product (RLD) in your application, Lamictal Tablets, 25 mg, 100 mg, 150 mg, and 200 mg, of GlaxoSmithKline (GSK), 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. 4,602,017 (the'017 patent) is scheduled to expire on July 22, 2008. Your ANDA contains a paragraph IV patent certification to '017 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lamotrigine Tablets, 25 mg, 100 mg, 150 mg, and 200 mg under this ANDA. Section 505(j)(5)(B) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against TEVA Pharmaceuticals USA (TEVA) for infringement of the '017 patent. This action must have been brought against TEVA prior to the expiration of 45 days from the date the notices you provided under paragraph (2)(B)(i) were received by the NDA/patent holder(s). You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that SmithKline Beecham Corporation (now GSK) initiated a patent infringement suit involving Lamotrigine Tablets, 25 mg, 100 mg, 150 mg, and 200 mg with respect to the '017 patent in the United States District Court for the District of New Jersey (SmithKline Beecham Corporation and Beecham Group, P.L.C. v. TEVA Pharmaceuticals USA, Civil Action No. 02-CV-3779). In a letter dated April 20, 2005, you informed the agency that a settlement agreement was reached between GSK and TEVA with respect to litigation on the '017 patent. This agreement allows generic entry of Lamotrigine Tablets, 25 mg, 100 mg, 150 mg and 200 mg to the U.S. market prior to the expiration of the '017 patent. We also acknowledge that the 30-month stay provided under section 505(j)(5)(B)(iii) of the Act expired on December 26, 2004.

With respect to 180-day generic drug exclusivity, we note that TEVA was the first ANDA applicant to submit a substantially complete ANDA for Lamotrigine Tablets 25 mg, 100 mg, 150 mg, and 200 mg with a paragraph IV certification to the 017 patent. Therefore, with this approval, TEVA is eligible for 180-days of market exclusivity for this drug product. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, 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 a correspondence to this application informing the agency of the date the exclusivity begins to run.[1]

[1] Because your ANDA was filed before the date of enactment on December 8, 2003 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) (Public Law 108-173), 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).

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 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,

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