



DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-420

Food and Drug Administration
Rockville MD 20857

JUN 21 2006

TEVA Pharmaceuticals USA
Attention: Philip Erickson
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 May 28, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Lamotrigine Tablets (Chewable, Dispersible), 5 mg and 25 mg.

Reference is made to your amendments dated July 15, 2003; January 20, 2004; January 5, and November 1, 2005; and February 6, March 14, March 28, April 11, May 23, May 26, June 5, and June 8, 2006. We also acknowledge receipt of your correspondence dated October 3, 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 the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Lamotrigine Tablets (Chewable, Dispersible), 5 mg and 25 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Lamictal Chewable, Dispersible Tablets, 5 mg and 25 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 Chewable, Dispersible Tablets, 5 mg and 25 mg, of GlaxoSmithKline (GSK), 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 No. 4,602,017 (the '017 patent)

is scheduled to expire on July 22, 2008 and U.S. Patent No. 5,698,226 (the '226 patent) is scheduled to expire on January 29, 2012. Your ANDA contains a paragraph IV patent certifications to the '017 and '226 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Lamotrigine Tablets (Chewable, Dispersible), 5 mg and 25 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 either of the listed patents. 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 (Chewable, Dispersible), 5 mg and 25 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-4537). No action for infringement of the '226 patent was brought against TEVA within the statutory 45-day period. In a letter dated April 20, 2005, you have 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 (Chewable, Dispersible), 5 mg and 25 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 February 16, 2005.

With respect to 180-day generic drug exclusivity, we note that TEVA was the first to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, TEVA is eligible for 180-days of market exclusivity. This exclusivity, which is provided for under section 505(j)(5)(8)(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

¹ Because your ANDA 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 application 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 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(s) 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,

A handwritten signature in black ink, appearing to read "Gary Buehler" with a stylized flourish at the end.

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