DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-690

AUG 3 2006

TEVA Pharmaceuticals USA
Attention: Philip Erickson
1090 Horsham Road
PO Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 14, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Venlafaxine Hydrochloride Tablets, 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg.

Reference is made to your amendments dated May 16, September 21, October 12, and December 28, 2005; and April 10, 2006. Reference is also made to your patent correspondence dated November 4, 2005, detailing the license agreement between TEVA Pharmaceuticals USA and Wyeth Pharmaceuticals, Inc.

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. Accordingly the ANDA is **approved**. The Division of Bioequivalence has determined your Venlafaxine Hydrochloride Tablets, 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Effexor of Wyeth Pharmaceuticals, Inc. (Wyeth). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Wyeth's Effexor Tablets 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg, is currently 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. 4,535,186 (the '186 patent) is scheduled to expire on June 13, 2008, with pediatric exclusivity added.

Your ANDA contains a paragraph IV certification to the '186 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Venlafaxine Hydrochloride Tablets 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 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 is brought against TEVA Pharmaceuticals USA (TEVA) for infringement of the '186 patent. You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against TEVA within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

The agency also recognizes that, with respect to the '186 patent, TEVA entered into an agreement with Wyeth providing TEVA with a limited license to manufacture and commercialize Venlafaxine Hydrochloride Tablets, 25 mg, 37.5 mg, 50 mg, 75 mg, and 100 mg, beginning on June 15, 2006.

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,

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