DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076565

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 10, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Venlafaxine Hydrochloride Extended-Release Capsules, 37.5 mg (base), 75 mg (base) and 150 mg (base).

Reference is also made to your amendments dated February 13, March 19, March 26, April 1, and April 10, 2003; April 1, and June 29, 2004; March 25, 2005; February 7, April 14, and August 14, 2006; April 27, June 22, September 18, and September 29, 2009; and April 7, April 23, May 17, May 19, June 1, June 7, June 11, June 15, and June 21, 2010.

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 Venlafaxine Hydrochloride Extended-Release Capsules, 37.5 mg (base), 75 mg (base) and 150 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Effexor XR Extended-release Capsules, 37.5 mg (base), 75 mg (base) and 150 mg (base), respectively, 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 "interim" dissolution specifications are as follows:

Equipment:	Apparatus 1 (Basket)
Volume:	900 mL
Medium:	Water
Stirring Rate:	100 rpm
Temperature:	37°C ± 0.5°C
Sampling Times:	3, 6, 16, and 24 hours

Specification:

Time (Hours)	% of the Labeled Amount Dissolved
3	NMT 40%
6	35 - 60%
16	60 - 85%
24	NLT 75%

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" if there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The RLD upon which you have based your ANDA, Wyeth's Effexor XR Extended-release Capsules, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,916,923 (the '923 patent)	December 28, 2013*
6,274,171 (the '171 patent)	September 20, 2017*
6,310,101 (the '101 patent)	June 28, 2013
6,403,120 (the '120 patent)	September 20, 2017*
6,419,958 (the '958 patent)	September 20, 2017*
6,444,708 (the '708 patent)	December 28, 2013*

*with pediatric exclusivity added

With respect to the '120 and '958 patents (treatment of depression), and the '171 and '708 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 of

Venlafaxine Hydrochloride Extended-Release Capsules, 37.5 mg (base), 75 mg (base) and 150 mg (base), 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 was brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. You have notified the agency that TEVA complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '171, '120, and '958 patents was brought against TEVA within the statutory 45-day period in the United States District Court for the District of New Jersey [Wyeth v. TEVA Pharmaceuticals USA, Inc. and TEVA Pharmaceutical Industries Ltd., Civil Action No. 03-1293]. You have notified the agency that on January 12, 2006, the litigation was dismissed.

With respect to the '120 and '958 patents (treatment of social anxiety disorder and generalized anxiety disorder), and the '923, and '101 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that these are method of use patents that do not claim any indication for which you are seeking approval.

With respect to 180-day generic drug exclusivity, we note that TEVA was the first ANDA applicant to submit a substantially complete ANDA with a paragraph IV certification to the '171, '120, and '958 patents. Therefore, with this approval, TEVA is eligible for 180 days of generic drug exclusivity for Venlafaxine Hydrochloride Extended-Release Capsules, 37.5 mg (base), 75 mg (base) and 150 mg (base). 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).[1] 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.

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[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).

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

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 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/U_CM072392.pdf

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-76565	ORIG-1	TEVA PHARMACEUTICALS USA INC	VENLAFAXINE HYDROCHLORIDE

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
06/28/2010
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.