DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-151/S-034
NDA 20-699/S-056

Wyeth Pharmaceuticals, Inc.
Attention: Kenneth R. Bonk
Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-1245

Dear Mr. Bonk:

Please refer to your supplemental new drug applications dated October 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor (venlafaxine hydrochloride) Immediate Release Tablets (NDA 20-151) and Effexor XR (venlafaxine hydrochloride) Extended Release Capsules (NDA 20-699).

We acknowledge receipt of your submission dated October 5, 2005.

Your submission of October 5, 2005 constituted a complete response to our action letter dated April 29, 2005.

The above supplemental applications provide for the following changes to product labeling:

1. Under **WARNINGS**, the following new section is added:
   Mydriasis *- Mydriasis has been reported in association with venlafaxine; therefore patients with raised intraocularpressure or at risk of acute narrow-angle glaucoma (angleclosure glaucoma) should be monitored (see PRECAUTIONS, Information for Patients).*

2. Under **PRECAUTIONS**, the existing subsection entitled "Mydriasis" has been removed.

3. Under **PRECAUTIONS/Information for Patients**, the following new section is added:
   Mydriasis *- Mydriasis (prolonged dilation of the pupils of the eye) has been reported with venlafaxine. Patients should be advised to notify their physician if they have a history of glaucoma or a history of increased intraocular pressure (see WARNINGS).*

In addition, it is noted that the adverse event term "angle-closure glaucoma" is currently listed under **ADVERSE REACTIONS/Postmarketing Reports** section.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your labeling submitted on October 5, 2005. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted on October 5, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDAs 20-151/S-034 and 20-699/S-056**." Approval of these submission by FDA are not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Dr. Renmeet Gujral, Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
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