DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-151 / S-043
NDA 20-699 / S-069

Wyeth Pharmaceuticals, Inc
Attention: Emmanuelle Magueur
P.O. Box 8299
Philadelphia, PA 19101

Dear Ms Magueur:

Please refer to your supplemental new drug applications dated February 27, 2006, 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).

Reference is also made to the Agency letter of October 20, 2006, requesting further revisions to the venlafaxine labelings, and to your responses submitted January 23, 2007. Specifically, the following new subsection under PRECAUTIONS/General has been added to each product labeling:

> *Interstitial Lung Disease and Eosinophilic Pneumonia*
> Interstitial lung disease and eosinophilic pneumonia associated with venlafaxine therapy have been rarely reported. The possibility of these adverse events should be considered in venlafaxine-treated patients who present with progressive dyspnea, cough, or chest discomfort. Such patients should undergo a prompt medical evaluation and discontinuation of venlafaxine therapy should be considered.

In addition, the adverse event term “pulmonary eosinophilia” has been removed from the ADVERSE REACTIONS/Postmarketing Reports section of labeling.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the submitted labeling text.

Please submit the content of the labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text within 21 days of the date of this letter. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

The final printed labeling (FPL) must be identical to the enclosed labeling. Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-151/S-043 and NDA 20-699/S-069.**" Approval of these submissions by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email Renmeet Grewal, Pharm.D., Regulatory Project Manager, at Renmeet.Grewal@FDA.HHS.GOV.

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

Enclosure (labeling)

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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