DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

SUPPLEMENT APPROVAL

NDA 20151 / S-053
NDA 20699 / S-086

Wyeth Pharmaceuticals, Inc.
Attention: Dr. Kimberly A. McCormick
Senior Manager, Global Regulatory Affairs
PO Box 8299
Philadelphia, PA 19101-8299

Dear Dr. McCormick:

Please refer to your supplemental new drug application dated and received December 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Effexor (venlafaxine HCl) Tablets and Effexor XR (venlafaxine HCl) Extended-Release Capsules.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the term "flu-like symptoms" under **PRECAUTIONS**, **General**, *Discontinuation of Treatment of Effexor* in the Effexor product line 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 enclosed labeling, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on December 3, 2008.

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20151 / S-053 and NDA 20699 / S-086.**"

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@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

Enclosures
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20151	SUPPL-53	WYETH PHARMACEUTICALS INC	EFFEXOR (VENLAFAXINE HCL) TABLETS
NDA-20699	SUPPL-86	WYETH PHARMACEUTICALS INC	EFFEXOR XR E-R CAPS.(VENLAFAXINE HCL)

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

/s/

MITCHELL V Mathis
11/09/2009
For Dr. Laughren