DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-699/S-038/S-043

Wyeth Pharmaceuticals
Attention: Tracy D. Rockney, JD
Director, Global Brand Management
Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-1245

Dear Ms. Rockney:

Please refer to the your supplemental new drug applications dated March 7, 2003 (S-043), and April 16, 2003 (S-038), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor XR (venlafaxine hydrochloride) Extended Release 37.5 mg, 75 mg, and 150 mg Capsules.

The above submissions, submitted as “Changes Being Effected” supplemental applications, provide for the following revisions to labeling:

S-043

- This supplement provides for revisions to the Effexor XR Patient Brief Summary to add the new indication of social anxiety disorder which was approved in an Agency letter dated February 11, 2003 under S-022 as well as the addition of the term "palpitation" under the list of most common side effects.

S-038

- This supplement provides for revisions to the Effexor XR Patient Brief Summary to add the term "seizures" to the list of discontinuation symptoms.

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 the submitted final printed labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 regarding this letter, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Russell Katz
9/2/03 04:48:00 PM