



NDA 20-151/S-044
NDA 20-699/S-071

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

Dear Mr. Bonk:

We acknowledge receipt of your supplemental new drug applications dated June 9, 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 an Agency letter dated May 9, 2006.

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **WARNINGS-Serotonin Syndrome, PRECAUTIONS-Information for Patients**, and **PRECAUTIONS-Drug Interactions** sections as requested in our letter dated May 9, 2006, based upon our review of drug interactions between SSRIs/SNRIs and triptans.

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 text.

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.

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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

Enclosure

**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
9/14/2006 04:12:19 PM