



NDA 20-151/S-038/S-039
NDA 20-699/S-062/S-064

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

Dear Mr. Bonk:

We acknowledge receipt of your supplemental new drug applications dated May 11 and 12, 2005 (NDAs 20-151/S-038 and 20-699/S-062), and August 9, 2005 (NDAs 20-151/S-039 and 20-699/S-064), 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.

Supplemental applications 20-151/S-038 and 20-699/S-062 submitted as "Changes Being Effected" supplemental applications, provide for the labeling addition of the terms "liver necrosis" to the OVERDOSAGE/Human Experience section of labeling as requested in an Agency letter dated February 28, 2005.

Supplemental applications 20-151/S-039 and 20-699/S-064 submitted as "Changes Being Effected" supplemental applications, provide for labeling revisions to Warnings-Sustained Hypertension section of labeling.

We have completed the review of your submissions, 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 labelings. Accordingly, these applications are approved effective on the date of this letter.

Additionally, please note that product labeling revisions submitted under NDAs 20-151/S-031/S-034 and 20-699/S-056/S-057, as "Changes Being Effected" supplemental applications, are still under review.

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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