



NDA 20-151/S-051

NDA 20-699/S-081

Wyeth Pharmaceuticals, Inc.
Attention: Kim McCormick, Pharm.D.
Senior Manager, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. McCormick:

We acknowledge receipt of your supplemental new drug applications dated December 13, 2007, and amended on December 19, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Effexor (venlafaxine HCl) Tablets (NDA 20-151) and Effexor XR (venlafaxine HCl) Extended-Release Capsules (NDA 20-699).

These supplemental new drug applications, submitted under "Changes Being Effected", provide for the following revisions to labeling:

1. Under **ADVERSE REACTIONS-Postmarketing Reports** section, revision of the terms "epidermal necrosis" to "toxic epidermal necrolysis".
2. Under the **HOW SUPPLIED** section, changes to reflect the discontinuation of several presentations.

We have completed our review of these applications, and they are approved, effective on the date of this letter.

We note that your structured product labeling (SPL) submitted on December 19, 2007, does not incorporate the most recent approved changes to your labeling. Therefore, we are requesting, within 21 days of the date of this letter, that you submit content of labeling [21 CFR 314.50(1)] in SPL format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the above proposed changes to product labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDA 20-151/S-051 and 20-699/S-081."

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

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If you have any questions, call LCDR Renmeet Grewal, Pharm. D., Senior 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
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/s/

Thomas Laughren
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