



NDA 20-151/S-047/S-049

NDA 20-699/S-077/S-079

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 June 29, 2007 (NDAs 20-151/S-047 & 20-699/S-077), and September 6, 2007 (NDAs 20-151/S-049 & 20-699/S-079), 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).

We additionally refer to an Agency letter dated August 7, 2007, requesting class labeling from all SSRI and SNRI sponsors pertaining to hyponatremia.

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

**NDAs 20-151/S-047 & 20-699/S-077**

- The addition of the adverse event terms "impaired balance" to the PRECAUTIONS, General, Discontinuation of treatment with Effexor, section of labeling.
- The addition of the adverse event terms "impaired coordination and balance" to the ADVERSE REACTIONS, Postmarketing Reports, section of labeling.

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- Revisions to the PRECAUTIONS, Hyponatremia and PRECAUTIONS, Geriatric Use sections of labeling as requested in an Agency letter dated August 7, 2007.

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.

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 Renmeet Grewal, Pharm. D., Regulatory Project Manager, at (301) 796-1080 or Bill Bender, Regulatory Project Manager, at 301-796-2145.

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

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/s/

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Thomas Laughren  
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