DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20151 / S-059
NDA 20699 / S-100

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Denise Tindle
Director, Worldwide Regulatory Strategy
445 Easter Point Road
Groton, CT 06340

Dear Ms. Tindle:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received March 23, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Effexor (venlafaxine HCl) Tablets and Effexor XR (venlafaxine HCl) Extended-Release Capsules.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the following new subsection of labeling: "Drug-Laboratory Test Interactions" under Drug Interactions:

Drug-Laboratory Test Interactions
False-positive urine immunoassay screening tests for phencyclidine (PCP) and amphetamine have been reported in patients taking venlafaxine. This is due to lack of specificity of the screening tests. False positive test results may be expected for several days following discontinuation of venlafaxine therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish venlafaxine from PCP and amphetamine.

We have completed our review of these supplemental applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

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If you have any questions, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff at Steven.Hardeman@FDA.GOV.

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(s): Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
05/03/2012
For Dr. Laughren