DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21992/S-001/S-006/S-007 **APPROVAL LETTER**

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

Dear Mr. Bonk:

We acknowledge receipt of your supplemental new drug applications dated April 4, 2008 (S-001), January 28, 2009 (S-006), and June 26, 2009 (S-007), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pristiq (desvenlafaxine) Extended-Release Tablets.

These supplemental new drug applications provide for the following changes to product labeling:

S-001 (submitted as a "Prior Approval" supplement)

1. A paragraph break was added after the first sentence in the last paragraph in Section 2 Dosage and Administration, 2.1 Initial Treatment of Major Depressive Disorder.
2. Additions to section 2 Dosage and Administration, 2.2 Special Populations in the Patients with Renal Impairment and Patients with Hepatic Impairment subsections. We additionally note that consistent changes were made to sections 8.7 (Hepatic Impairment), 12.6 (Special Populations-Hepatic Insufficiency), and 12.6 (Special Populations-Renal Insufficiency).
3. Revisions to Section 5 Warnings and Precautions, 5.3 Elevated Blood Pressure.
4. Revisions to Sections 6 Adverse Reactions, 6.1 Clinical Studies Experience.
5. Revisions to Section 14 Clinical Studies.

S-006 (submitted as a "Changes Being Effected" supplement)

- Revisions in the text to note orthostatic hypotension changes in the elderly population, i.e., Use in Specific Populations subsection of the Highlights section, 6.1 Clinical studies Experience section, and 8.5 Geriatric Use section.

S-007 (submitted as a "Prior Approval" supplement)

- Deletion of "*(by giving 50 mg of Pristiq less frequently)"* from Section 2.4 Discontinuing Pristiq.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and Medication Guide). 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 NDA 21992/S-001/S-006/S-007."

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, email Juliette Touré, PharmD, Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.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: Product Labeling & Medication Guide

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

/s/

THOMAS P LAUGHREN
08/31/2009