**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Food and Drug Administration Silver Spring MD 20993**

NDA 021992/S-015 **SUPPLEMENT APPROVAL**

Wyeth Pharmaceuticals, Inc.
Attention: Kenneth R. Bonk
Director II, Global Regulatory Affairs
PO Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Bonk:

We acknowledge receipt of your supplemental new drug application dated and received June 3, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pristiq (desvenlafaxine) Extended-Release Tablets.

This supplemental application, submitted as a "Changes Being Effected" supplement, provides for revisions to include severe cutaneous reactions in the reference safety information section 6.3 "Adverse Reactions Reported With Other SNRI's".

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

(b) (4)

**LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

**REPORTING REQUIREMENTS**

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

If you have any questions, call LCDR Juliette Toure, PharmD, at (301) 796-1924.

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: Content of Labeling

| Application Type/Number | Submission Type/Number | Submitter Name | Product Name |
|---|---|---|---|
| NDA-21992 | SUPPL-15 | WYETH PHARMACEUTICALS INC | PRISTIQ (DESVENLAFAXINE) EXTENDED-RELEAS |

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

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/s/

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THOMAS P LAUGHREN
07/09/2010