DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

SUPPLEMENT APPROVAL

NDA 21992 / S-009

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

Dear Mr. Bonk:

Please refer to your supplemental new drug application dated and received October 8, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pristiq (desvenlafaxine) Extended-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for the following labeling change (additions/changes underlined):

> **6.2 Adverse Reactions Identified During Post-Approval Use**
>
> The following adverse reaction has been identified during post-approval use of PRISTIQ. Because post-approval reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure:
>
> *Skin and subcutaneous tissue disorders* – Angioedema.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on October 8, 2009.

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 21992 / S-009**."

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21992	SUPPL-9	WYETH PHARMACEUTICALS INC	PRISTIQ (DESVENLAFAXINE) EXTENDED-RELEAS

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
11/09/2009
For Dr. Laughren