DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21992 / S-011 **SUPPLEMENT APPROVAL**

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 December 22, 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):

> **6.3 Adverse Reactions Reported With Other SNRIs**
>
> Although the following are not considered adverse reactions for desvenlafaxine succinate, they are adverse reactions for other SNRIs and may also occur with desvenlafaxine succinate: gastrointestinal bleeding, hallucinations, and photosensitivity reactions.

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 December 22, 2009.

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-11	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/

THOMAS P LAUGHREN
02/16/2010