DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-992/S-005

Wyeth Pharmaceuticals Inc.
Attention: Beth Kendsersky
Director II, Regulatory CMC
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Kendsersky:

Please refer to your supplemental new drug application dated December 23, 2008, received December 23, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pristiq® (desvenlafaxine) Tablets.

This "Prior Approval" supplemental new drug application provides for a change from the currently registered film coating agent, **(b) (4)** Pink for Pristiq 50 mg tablet strength.

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

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, except for the inclusion of the NDC numbers for the 50 mg tablets. 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 21-922/S-005."

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, call Teshara Bouie, Regulatory Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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

/s/

Jim Vidra

4/23/2009 05:03:47 PM