DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21992/S-034

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.
Attention: Mary A. Pias
Associate Director, Regulatory Strategy
445 Eastern Point Road
Groton, CT 06340

Dear Ms. Pias:

Please refer to your Supplemental New Drug Application (sNDA) dated May 1, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pristiq (desvenlafaxine) Extended-Release 50 and 100 mg Tablets..

We acknowledge receipt of your amendments dated August 10, 2012, and September 21, 2012.

This "Prior Approval" supplemental new drug application provides for class labeling revisions to the **Dosage and Administration**, **Contraindications**, **Warnings and Precautions**, **Drug Interactions**, **Patient Counseling Information**, & **Medication Guide** regarding serotonin toxicity associated with the co-administration of linezolid and methylene blue as requested in an Agency supplement request letter dated March 5, 2012.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revisions agreed upon in an email communication dated December 5, 2012, between you and Paul David, of this Agency.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to, except with the revisions agreed upon in the September 24, 2012 communication, the enclosed labeling (text for the package insert, and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, email CDR Juliette Touré, Pharm.D., Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

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
12/07/2012