DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021992/S-030

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer
Attention: Maria Pias
Associate Director
Worldwide Regulatory Strategy, Pfizer
PO Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Pias:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 20, 2011, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pristiq (desvenlafaxine) 50 mg, 100 mg Extended-Release Tablets.

We also refer to the Agency's "Changes Being Effected" supplement request letter sent to you on September 21, 2011, requesting revisions to add **bruxism** to section 6.2 Adverse Reactions Identified During Post-Approval Use as well as the addition of information to section 7.10 Drug Laboratory Test Interactions on false-positive urine immunoassay screening tests for patients taking Pristiq.

This "Changes Being Effected" supplemental new drug application proposes the addition of **bruxism** to section 6.1 Clinical Studies Experience under Psychiatric Disorders as well as the addition of information to section 7.10 Drug Laboratory Test Interactions on false-positive urine immunoassay screening tests for patients taking Pristiq.

In an email correspondence dated October 7, 2011, we agreed to your proposal to include bruxism in section 6.1 Clinical Studies Experience under Psychiatric Disorders, rather than in section 6.2, since the occurrence of bruxism was observed during clinical trials.

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.

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 listed, the enclosed labeling (text for the package insert), 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/DrugsGuidanceComplianceRegulatroyInformation/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 Juliette Touré, Senior Regulatory Project Manager, at Juliette.Toure@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

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
03/07/2012