DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021992/S-039

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING COMMITMENT

Pfizer Inc.
Attention: Maria A. Pias
Associate Director, Worldwide Regulatory Strategy
445 Eastern Point Road
Groton, CT 06340

Dear Ms. Pias:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 25, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Pristiq (desvenlafaxine) 25 mg, 50 mg, 100 mg Extended-Release Tablets.

We acknowledge receipt of your amendments dated July, 18, 2014, July 28, 2014, and August 5, 2014.

We also refer you to our February 29, 2008 Approval letter in which you agreed to explore lower dose response for effectiveness of lower strengths as a postmarketing commitment.

This supplemental new drug application provides for revisions to the labeling for Pristiq for the 25 mg lower dose strength.

APPROVAL & LABELING

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 the enclosed labeling (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 that includes labeling changes 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).

FULFILLMENT OF POSTMARKETING COMMITMENT

Your April 25, 2014 submission contains the final report for the following postmarketing commitment listed in the February 29, 2008 approval letter.

1229-2 Your NDA for desvenlafaxine succinate (DVS) demonstrates the effectiveness of doses as low as 50 mg as a treatment for Major Depressive Disorder (MDD), however, the available data for effectiveness for this drug in MDD suggests a flat dose response curve for efficacy between 50 and 400 mg/day. On the other hand, there is a clear dose response for adverse events as the dose increases from 50 to 400 mg/day. Therefore, there is a need to better understand the lower end of the dose response curve to determine if efficacy might be achieved at doses even lower than 50 mg/day. You have agreed to conduct and submit the results of a randomized controlled study including placebo and DVS doses of 10, 25, and 50 mg/day as a Postmarketing commitment. This study will assess efficacy in this dose range and will also include a validated and reliable outcome measure to assess for sexual dysfunction. You have agreed to submit the results of this trial no later than 3 years after the date of the approval for this NDA.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there is a postmarketing requirement listed in the February 29, 2008, approval letter that is still open.

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 CAPT Bill Bender, Senior Regulatory Project Manager, at william.bender@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
Content of Labeling
Carton 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
08/20/2014