



NDA 19839/S-079
NDA 20990/S-038

SUPPLEMENT APPROVAL

Pfizer Pharmaceuticals, Inc.
Attention: James H. Medley, Ph.D.
Acting Regulatory Strategist
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. Medley:

Please refer to your Supplemental New Drug Applications (sNDA) dated April 21, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zoloft (sertraline hydrochloride) 25mg, 50mg, and 100mg Tablets (NDA 19839), and Zoloft (sertraline hydrochloride) 20mg/mL Oral Concentrate (NDA 20990).

We acknowledge receipt of your amendment dated May 22, 2012.

The May 22, 2012, submission constituted a complete response to our February 27, 2012, action letter.

These "Changes Being Effected" supplemental new drug applications provide for the addition of the terms "diabetes mellitus" to the **Other Events Observed During the Post marketing Evaluation of ZOLOFT** subsection under **ADVERSE REACTIONS**.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed 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 (text for the package insert, 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).

Additionally, we have incorporated your proposed changes submitted under “Changes Being Effected” in supplements 19839/S-080 and 20990/S-039. These changes are still pending review with the Agency. We request that you amend these supplements to incorporate the changes approved in this letter as well as the changes approved in our approval letter dated December 18, 2012.

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, please email Shin-Ye Sandy Chang, Regulatory Project Manager, at shinye.chang@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
02/01/2013