DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19839/S-073/S-081
NDA 20990/S-034/S-040

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 Application (sNDA) dated July 28, 2010 (NDA 19839 S-073, NDA 20990 S-034) and April 5, 2012 (NDA 19839 S-081, NDA 20990 S-040), 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 amendments dated December 27, 2011, June 15, 2012, July 15, 2012, August 10, 2012, and September 12, 2012.

These "Prior Approval" supplemental new drug applications provide for class labeling revisions to the **Contraindications**, **Warnings, Precautions**, **Dosage and Administration, and Medication Guide** sections regarding serotonin toxicity associated with the co-administration of linezolid and methylene blue as well as revisions related to persistent pulmonary hypertension of the newborn as requested in Agency supplement request letters dated March 2, and 5, 2012 and further revised on July 6, 2012, September 4, 2012, and November 29, 2012.

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, agreed upon labeling text and with the minor editorial revisions agreed upon in an email communication dated December 12, 2012, between you and Shin-Ye Sandy Chang, 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 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).

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(S): 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
12/18/2012