



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-839/S-068

NDA 20-990/S-031

Pfizer Pharmaceuticals
Attention: Amanda Radola
Manager, Regulatory Affairs
235 East 42nd Street
New York, NY 10017-3184

Dear Ms. Radola:

We acknowledge receipt of your supplemental new drug applications dated January 31, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoloft (sertraline hydrochloride) 25 mg, 50 mg, and 100 mg tablets (19-839) and 20 mg/ml oral concentrate (20-990).

Reference is also made to an Agency letter dated January 3, 2008, requesting class labeling revisions to your product labeling related to abnormal bleeding.

This supplement, submitted as a "Changes Being Effected" application, provides for revisions to the PRECAUTIONS, Information for Patients, and Drug Interactions sections regarding abnormal bleeding as requested by the Agency in our letter dated January 3, 2008. Additionally, we note that you have incorporated our changes, verbatim.

We have completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Renmeet Gujral, Regulatory Project Manager, at (301) 796-1080.

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Mitchell Mathis
3/6/2008 09:56:12 AM
For Dr. Laughren