DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-839/S-047/S-050
NDA 20-990/S-013/S-017

Pfizer Pharmaceuticals
Attention: Mojgan Moghaddassi, Pharm.D.
Drug Regulatory Affairs
235 East 42nd Street
New York, NY 10017-3184

Dear Dr. Moghaddassi:

Please refer to your supplemental new drug applications, NDAs 19-839/S-047 & 20-990/S-013, dated February 26, 2003, 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).

We additionally reference an Agency action letter dated December 23, 2003, as well as communications between the Agency and Pfizer dated July 16, and 23, 2004.

We acknowledge receipt of your submission dated July 29, 2004. Your submission of July 29, 2004 constituted a complete response to our December 23, 2003 action letter.

We additionally acknowledge receipt of your supplemental applications, NDAs 19-839/S-050 & 20-990/S-017, dated May 28, 2004.

These supplemental new drug applications provide for the following changes to product labeling:

19-839/S-050 & 20-990/S-017

1. The addition of a new subsection under **WARNINGS** entitled **Clinical Worsening and Suicide Risk**.
2. Revisions to the **PRECAUTIONS-Information for Patients** section.
3. Delete the section in **PRECAUTIONS-General** entitled "Suicide".
4. Add a reference to the **WARNINGS** section at the end of the **PRECAUTIONS-Pediatric Use** section, i.e., (see **WARNINGS-Clinical Worsening and Suicide Risk**).

19-839/S-047 & 20-990/S-013

1. Revisions to the **PRECAUTIONS-Use in Patients with Concomitant Illness** section of labeling to incorporate the results of the Zoloft SADHART clinical trial.
2. The addition of a new subsection entitled **Discontinuation of Treatment with Zoloft** in the **PRECAUTIONS-General** section as requested in our December 23, 2003 letter.
3. The addition of a new subsection entitled **Abnormal Bleeding** in the **PRECAUTIONS-General** section as requested in our December 23, 2003 letter.
4. The addition of an abnormal bleeding paragraph in the **PRECAUTIONS-Information for Patients** section as requested in our December 23, 2003 letter.
5. The addition of a new subsection entitled **Drugs That Interfere With Hemostasis (Non-selective NSAIDs, Aspirin, Warfarin, etc.)** in the **PRECAUTIONS-Drug Interactions** section as requested in our December 23, 2003 letter.
6. The addition of a new subsection entitled **Pregnancy-Nonteratogenic Effects** in the **PRECAUTIONS-Pregnancy** section as requested in our December 23, 2003 letter.
7. The addition of a new subsection entitled **Treatment of Pregnant Women During the Third Trimester** in the **DOSAGE AND ADMINISTRATION-Special Populations** section as requested in our December 23, 2003 letter.
8. The addition of a new subsection entitled **Discontinuation of Treatment with Zoloft** in the **DOSAGE AND ADMINISTRATION** section as requested in our December 23, 2003 letter.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul David, Senior Regulatory Health Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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/

Russell Katz

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