DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-839/S-070
NDA 20-990/S-032

Pfizer, Inc.
Attention: Amanda Radola
Associate Director, World Wide Regulatory Affairs
235 East 42nd Street
New York, NY 10017

Dear Ms. Radola:

We acknowledge receipt of your supplemental new drug applications dated January 26, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoloft (sertraline HCl) Tablets and Oral Concentrate.

Reference is also made to an FDA letter dated December 4, 2008 notifying you, under section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Zoloft. This information pertains to the risk of neuroleptic malignant syndrome associated with use of selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs), including Zoloft.

We additionally refer to an e-mail from LCDR Renmeet Grewal, of the FDA, to you dated January 23, 2009, requesting additional revisions to the labeling.

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 submitted labeling text.

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

LETTERS TO HEALTH CARE PROFESSIONALS

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

5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call Renmeet Grewal, Pharm. D., Senior 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/

Thomas Laughren

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