DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-839/S-057
NDA 20-990/S-023

Pfizer Inc.
Attention: Mojgan Moghaddassi, Pharm.D.
Senior Manager, U.S. Regulatory Affairs
235 E. 42nd Street
New York, NY 10017

Dear Dr. Moghaddassi:

We acknowledge receipt of your supplemental new drug applications dated December 29, 2005 submitted under section 505(b) of the Federal Food Drug and Cosmetic Act for Zoloft (sertraline hydrochloride) tablets (NDA 19-839) and Zoloft (sertraline hydrochloride) oral concentrate (NDA 20-990).

These "Changes Being Effected" supplemental new drug applications provide for the following additions to the **PRECAUTIONS-Drug Interactions-***CNS Active Drugs* section of product labeling:

> **PRECAUTIONS-Drug Interactions-***CNS Active Drugs*
>
> Results of a placebo-controlled trial in normal volunteers suggest that chronic administration of sertraline 200 mg/day does not produce clinically important inhibition of phenytoin metabolism. Nonetheless, at this time, it is recommended that plasma phenytoin concentrations be monitored following initiation of Zoloft therapy with appropriate adjustments to the phenytoin dose, particularly in patients with multiple underlying medical conditions and/or those receiving multiple concomitant medications.
>
> The effect of Zoloft on valproate levels has not been evaluated in clinical trials. In the absence of such data, it is recommended that plasma valproate levels be monitored following initiation of Zoloft therapy with appropriate adjustments to the valproate dose.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your labeling submitted on December 29, 2005. Accordingly, these supplemental applications are approved effective on the date of this letter.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Renmeet Gujral, Pharm. D., 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

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

5/4/2006 03:26:46 PM