DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDAs 19-839/S-065 & 20-990/S-029

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

Dear Ms. Radola:

We acknowledge receipt of your supplemental new drug applications dated September 6, 2007, 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 refer to an Agency letter dated August 7, 2007, requesting class labeling from all SSRI and SNRI sponsors pertaining to hyponatremia.

These new drug applications, submitted under "Changes Being Effected" provide for the following revisions to labeling:

- Revisions to the PRECAUTIONS, Hyponatremia and PRECAUTIONS, Geriatric Use sections of labeling as requested in on Agency letter dated August 7, 2007.

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 agreed-upon labeling text.

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., Regulatory Project Manager, at (301) 796-1080 or Bill Bender, Regulatory Project Manager, at 301-796-2145.

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
10/4/2007 09:16:39 AM