CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-839/S-044

20-990/S-010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-839/S-044
NDA 20-990/S-010

Pfizer Inc.
Attention: Alan J. Dunbar
Director, Worldwide Regulatory Strategy
235 E. 42nd Street
NY, NY 10017

Dear Mr. Dunbar:

Please refer to your supplemental new drug applications dated December 14, 2001, received December 17, 2001, 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 June 19, 2003.

We acknowledge receipt of your submissions dated June 26, July 18, and July 28, 2003. Your submission of July 18, 2003 constituted a complete response to our June 19, 2003 action letter.

These "Prior Approval" supplemental new drug applications provide for additional safety data in the pediatric population.

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 note your agreement to the attached labeling in an electronic communication between Mr. Paul David, of the Agency, and yourself dated September 12, 2003.

The final printed labeling (FPL) must be identical to the agreed upon enclosed labeling (text for the package insert).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements

NDAs 19-839/S-044 & 20-990/S-010." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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
9/16/03 08:38:14 AM