DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-839/S-034/S-036
NDA 20-990/S-002/S-004

Pfizer Pharmaceuticals
Attention: Graydon A. Elliott
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-3184

Dear Mr. Elliott:

Please refer to your May 26, 2000 supplemental new drug applications 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 (NDA 19-839) and 20 mg/ml Oral Concentrate (NDA 20-990).

We acknowledge receipt of your submission dated April 29, 2002. Your submission of April 29, 2002, constituted a complete response to our March 1, 2002 action letter.

These supplemental applications provide for labeling revisions to include prevention of relapse following long-term treatment of obsessive compulsive disorder (NDA 19-839/S-034 and 20-990/S-002) and prevention of relapse following long-term treatment of panic disorder (NDA 19-839/S-036 and 20-990/S-004).

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 submitted final printed labeling (package insert submitted April 29, 2002; Label Code 69-4721-00-2). Accordingly, these supplemental applications are approved effective on the date of this letter.

We additionally refer to an Agency letter dated September 18, 2002, sent to NDAs 19-839/S-043 and 20-990/S-009, providing for the approval of changes to the Zoloft labeling regarding a Zoloft and pimozide drug interaction. Since the final printed labeling submitted in your April 29, 2002 submission did not incorporate the changes provided for in our September 18, 2002 letter, we are requesting that you resubmit final printed labeling.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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, these submissions should be designated "FPL for approved supplement NDAs 19-839/S-034/S-036 & 20-990/S-002/S-004." Approval of these submissions 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 a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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, R.Ph., Regulatory 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

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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