



NDA 19-839/S-055

NDA 20-990/S-022

Pfizer Pharmaceuticals
Attention: Mojgan M. Moghaddassi, Pharm.D.
Regulatory Affairs
235 East 42nd Street
New York, NY 10017-3184

Dear Dr. Moghaddassi:

We acknowledge receipt of your supplemental new drug applications dated April 15, 2005, 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).

These "Changes Being Effected" supplemental new drug applications provide for revisions to the HOW SUPPLIED section for the addition of the NDC numbers and bottle size of the upcoming 30 count bottles for the 25, 50 and 100 mg tablets.

We completed our review of these applications, and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 15, 2005).

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDAs 19-839/S-055 & 20-990/S-022.**" Approval of these submissions by FDA is not required before the labeling is used.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Acting 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
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