20990

NDX

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020990

Trade Name: ZOLOFT 20MG/ML ORAL CONCENTRATE

Generic Name: SERTRALINE HYDROCHLORIDE

Sponsor: PFIZER PHARMACEUTICALS

Approval Date: 12/07/1999

INDICATION(s): TREATMENT OF DEPRESSION

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APPLICATION for: 020990

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter			X	
Approvable Letter	X			
Final Printed Labeling	X			
Medical Review(s)	X			
Chemistry Review(s)	X			
EA/FONSI			X	
Pharmacology Review(s)			X	
Statistical Review(s)			X	
Microbiology Review(s)	X			
Clinical Pharmacology Biopharmaceutics Review(s)	X			
Bioequivalence Review(s)			X	
Administrative Document(s)/ Correspondence	X			

APLTR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 20-990

Pfizer Pharmaceuticals
Attention: Mary Kuskin, R.Ph.
Drug Regulatory Affairs
235 East 42nd Street
New York, New York 10017-3184

Dear Ms. Kuskin:

Please refer to your New Drug Application dated April 15, and received April 16, 1998, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoloft (sertraline hydrochloride) 20 mg/ml oral concentrate.

We acknowledge receipt of your submission dated June 4, 1999. This submission constituted a complete response to our April 15, 1999 approvable letter.

We also acknowledge receipt of your additional communications dated October 1, October 12, and October 29, 1999.

This new drug application provides for a new oral concentrate formulation of sertarline hydrochoride.

We have completed our review of this application, 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 attached draft labeling. Accordingly, the application is approved effective as of the date of this letter.

LABELING

Accompanying this letter (Attachment) is the final labeling for Zoloft Oral Concentrate. We note your agreement to this labeling in a telephone conversation dated November 30, 1999, between Mr. Paul David, of this Agency, and Dr. Martha Brumfield of Pfizer. In addition to the labeling revisions to reflect this new oral concentrate formulation, the labeling includes the following additions: 1) addition of a sumatriptan interaction paragraph in the Precautions section (submitted as pending supplement 016), 2) the addition of the data from your renal and hepatic studies (submitted as pending supplement 025), and 3) the addition of a sexual dysfunction paragraph in the Adverse Reactions section (submitted as pending supplement 028), and the corrections to Table 3 in the Adverse Reactions section. Revisions to labeling are denoted using a double underline font.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC)

1. Expiration Date

   The Agency is approving an expiry date of 24 months at this time.

2. Methods Validation

   Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 FR 66632). We note that you are in the process of fulfilling your pediatric study requirement at this time.

Please submit 20 copies of the final printed labeling ten of which are individually mounted on heavy weight paper or similar material. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-990." Approval of this submission by FDA is not required before the labeling is used.

Additionally, please submit one market package of the drug product when it is available.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 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, please contact Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely yours,

/S/

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ATTACHMENT