

19-839 / S-026

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION for: 019839/S026

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			



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NDA 19-839/S-026

Food and Drug Administration
Rockville MD 20857

Pfizer Inc.
Attention: Margaret Longshore
Director, Regulatory Affairs
235 E. 42nd Street
New York, New York 10017

DEC - 7 1999

Dear Ms. Longshore:

Please refer to your supplemental new drug application dated October 7, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoloft[®] (sertraline hydrochloride) Tablets.

This supplement provides for the use of Zoloft[®] Tablets for the treatment of post-traumatic stress disorder as a new indication.

We also refer to your resubmission dated September 10, 1999.

We acknowledge receipt of your correspondence dated November 1, 19, and 30, 1999; and December 2 and 3, 1999.

We have completed the review of this supplemental application, 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 enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The labeling accompanying this letter should be used for marketing this drug product. This final labeling is based upon your labeling proposal for the PTSD indication agreed upon on October 29, 1999, and additional statements related to safety involved with NDA 20-990, agreed upon on November 30, 1999, with the Agency. It is identical to your final labeling proposal dated December 3, 1999, with minor changes to Table 3 and Table 4, agreed to on December 6, 1999, by the Agency.

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

Please submit 20 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 supplement NDA 20-031/S-023." Approval of this submission by FDA is not required before the labeling is used.

Phase 4 Commitment:

Since post-traumatic stress disorder is regarded as a chronic disease and continued treatment of patients is expected beyond several months, we are interested in reviewing the results of a study which addresses the issue of long-term efficacy. In this regard, we note your November 1, 1999, commitment to submit the results of a long-term relapse prevention trial for our review.

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. If an IND is not required to meet your Phase 4 commitments, please submit protocols, data and final reports to this NDA as correspondence. In addition, under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include the number of patients entered in each study, expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated: "Phase 4 Commitments."

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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

In addition, since we believe that post-traumatic stress disorder is also found in the pediatric population and, once approved for this indication, Zoloff[®] will likely be used in pediatric patients, we recommend that you conduct adequate and well-controlled trials for this disorder in this population.

In this regard, please 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 have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). However, in the interim, please submit your pediatric drug development plans within 120 days from the date of this letter unless you believe a waiver is appropriate.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" in addition to your plans for pediatric drug development described above. If you do not submit a Proposed Pediatric Study Request within 120 days from the date of this letter, we will presume that you are not interested in obtaining pediatric exclusivity [NOTE: You should still submit a pediatric drug development plan.] and will notify you of the pediatric studies that are required under section 21 CFR 314.55. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity.

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, contact Anna Marie Homonnay-Weikel, R.Ph., Regulatory Project Manager, at (301) 594-5535.

Sincerely,

/s/

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

APPEARS THIS WAY
ON ORIGINAL

Attachment

APPEARS THIS WAY
ON ORIGINAL