



NDA 19-839/S-045 & 20-990/S-011

Pfizer, Inc.  
Attention: Alan Dunbar  
Director, Worldwide Regulatory Strategy  
235 East 42<sup>nd</sup> Street 150/7/100  
New York, NY 10017

Dear Mr. Dunbar:

Please refer to your supplemental new drug application dated January 18, 2002, received January 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoloft® (sertraline hydrochloride) Tablets and Oral Concentrate.

We acknowledge receipt of your amendments dated December 11, 2002 (revised draft labeling).

Your submission of December 11, 2002, constituted a complete response to our November 19, 2002, action letter.

This supplemental new drug application provides for the use of Zoloft® (sertraline hydrochloride) Tablets and Oral Concentrate for the treatment of social anxiety disorder as a new indication.

We also refer to a January 24, 2003, telephone conversation between you and Ms. Anna Marie H. Weikel of this Division, during which it was agreed that the term '(b)(4)-----' would be deleted from the heading for Social Anxiety Disorder in the 'Clinical Trials' section as indicated in the enclosed labeling.

We have completed the review of this supplemental 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 enclosed labeling text dated December 11, 2002, with the agreed upon change. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit the copies of final printed labeling (FPL) electronically 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, this submission should be designated "FPL for approved supplement NDA 19-839/S-045 & 20-990/S-011." Approval of this submission by FDA is not required before the labeling is used.

FDA's Pediatric Rule [at 21 CFR 314.55/21 CFR 601.27] was challenged in court. On October 17, 2002, the court ruled that FDA did not have the authority to issue the Pediatric Rule and has barred FDA from enforcing it. Although the government decided not to pursue an appeal in the courts, it will work with Congress in an effort to enact legislation requiring pharmaceutical manufacturers to conduct appropriate pediatric clinical trials. In addition, third party interveners have decided to appeal the court's decision striking down the rule. Therefore, we encourage you to submit a pediatric plan that describes development of your product in the pediatric population where it may be used. Please be aware that whether or not this pediatric plan and subsequent submission of pediatric data will be required depends upon passage of legislation or the success of the third party appeal. In any event, we hope you will decide to submit a pediatric plan and conduct the appropriate pediatric studies to provide important information on the safe and effective use of this drug in the relevant pediatric populations.

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 should have any questions, please call Ms. Anna Marie H. Weikel, R.Ph., Senior Regulatory Project Manager, at (301) 594-5535.

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



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/s/

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Russell Katz  
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