



NDA 19-839, S-039

NDA 20-990, S-007

Pfizer Inc.  
Attention: Graydon Elliott  
Director, Worldwide Regulatory Strategy  
235 East 42nd Street  
New York, New York 10017-5755  
USA

Dear Mr. Elliott:

Please refer to your supplemental new drug applications (sNDAs) dated January 31, 2001, received February 1, 2001 submitted under section 505(b) pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Zoloft (sertraline) tablets, Zoloft (sertraline) oral concentrate, Zoloft (sertraline) oral concentrate. These supplemental applications provide for the use of Zoloft Tablets and Zoloft Oral Concentrate in the treatment of Premenstrual Dysphoric Disorder (PMDD).

Please also refer to our action letter of November 28, 2001, which found these submissions approvable; this letter provided detailed information on the issues needing resolution before the applications could be approved.

Your subsequent submission of December 21, 2001, which was received by this Agency on December 26, 2001, constituted a complete response to our November 28, 2001 action letter. We also acknowledge receipt of your submissions dated February 19, 2002, April 18, 2002, May 1, 2002, and May 2, 2002. These submissions were reviewed for this action, with the exception of the Patient Package Insert provided in the May 1 submission, and the promotional materials provided on May 2. We will discuss these two submissions in a later section of this letter.

#### **Approval of Supplemental Applications**

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

#### **Request for Submission of Final Printed Labeling (FPL)**

The final printed labeling (FPL) must be identical to the enclosed (see electronic copy) agreed-upon labeling text and to the immediate container and carton labels as submitted on December 21, 2001 and May 1, 2002. We have provided a clean copy of the agreed-upon text for your reference. Marketing the product with FPL that is not identical to the approved labeling text may render the products misbranded, and unapproved new drugs. Please note that we will address the Patient Package Insert, as well as the promotional materials submitted, in separate correspondence, but that your applications are approved with respect to the Physician's Package Insert and immediate container / carton labeling provided and referenced herein.

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 ten of the paper copies on heavy-weight paper or similar material. For administrative purposes, please designate these submissions “FPL for approved supplemental NDA 19-839 / S-039 and 20-990 / S-007”. Approval of this labeling submission by FDA is not required before the labeling is used.

### **Pediatric Exclusivity and Pediatric Studies in This Indication**

As you are aware, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (21 CFR 314.55).

You have previously been informed that Zoloft, as the chemical entity sertraline hydrochloride, has been granted six months’ pediatric exclusivity as of February 1, 2002. This has been granted under the provisions of Pediatric Exclusivity and does not pre-empt the need for further studies of sertraline hydrochloride in the adolescent PMDD patient population.

We note your submission of a Pediatric Update to these supplemental NDAs on April 18, 2002. This update included information as requested in our action letter of November 28, 2001. The information in this update will be reviewed and comments conveyed to your firm, if appropriate, via separate correspondence.

### **Status of Promotional Materials for This Indication**

We note that your May 2, 2002 submission, acknowledged above, includes advance copies of voluntarily provided introductory promotional materials that you propose to use for Zoloft in the indication PMDD. We also note that one copy of this information has been provided to the Division of Drug Marketing, Advertising, and Communications. You will be informed via separate correspondence of any issues, requests, or concerns the Agency may have related to these materials.

### **NDA Reporting Requirements**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81). In addition, if you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA, and a copy to the following address:

MEDWATCH, HF-2  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

If you have any questions about this letter, please contact Doris J. Bates, Ph.D., at 301-594-2850.

Sincerely,

*[see electronic signature page]*

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

[Attachment: electronic copy of agreed-upon labeling text]

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Russell Katz  
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