HFD-104

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 19-839

FEB 28 2000

Pfizer Pharmaceuticals
Attention: Andrew G. Clair, Ph.D.
Director, Drug Regulatory Affairs
235 East 42nd Street
New York, New York 10017-3184

Dear Dr. Clair:

Please refer to your New Drug Application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zoloft (sertraline hydrochloride) tablets.

We additionally refer to an Agency pediatric Written Request letter dated April 28, 1999, and to Agency letters dated May 18, and August 10, 1999 (b) (4)

We acknowledge receipt of your submission dated October 7, 1999, providing for proposed changes in the Written Request for pediatric studies.

We have reviewed your proposed changes and are amending the below listed sections of the Written Request. All other terms stated in our Written request issued on April 28, 1999, remain the same.

- **Age Group in Which Study(ies) will be Performed – All Studies**

  We are amending this section to provide for the minimum age for the two efficacy studies to be extended from seven to six years old.

- **Types of Studies, Study Design, Number of Patients to be Studied or Power of Study to be Achieved, Study Endpoints, Statistical Information, and Study Evaluations**

  All references to conducting or analyzing separate pharmacokinetic or safety studies are removed. We concur with your assertion that this information has been previously submitted when Zoloft was approved for OCD in the pediatric and adolescent population.

All of your other proposed changes to the Written request including 1) employing a flexible dose design in your placebo controlled studies and 2) indicating the CDRS-R as the primary outcome measurement have not been accepted and are not terms of the Written Request.

Reports of the studies that meet the terms of the Written Request dated April 28, 1999, as amended by this letter must be submitted to the Agency on or before April 28, 2002 to possibly qualify for a pediatric exclusivity extension under section 505A of the Federal Food, Drug, and Cosmetic Act.

Reports of the studies should be submitted as a supplement to your approved NDA with the proposed labeling changes you believe would be warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED**" in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. Please also send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked "**PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES**" in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed upon by the Agency.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

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

Sincerely yours,

RT 2/24/03

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Archival NDA 19-839
HFD-120/Div
HFD-170/Div
HFD-100/RTemple
HFD-120/PDavid
HFD-120/RKatz/TLaughren/AMosholder/RGlass
HFD-600/Office of Generic Drugs
HFD-2/MLumpkin
HFD-104/DMurphy
2/16/00
filename: ZOLOFT\AMENDED PEDIATRIC WR 10-7-99.DOC

PEDIATRIC WRITTEN REQUEST LETTER
INFORMATION REQUEST (IR)