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Pfizer Global Pharmaceuticals

Mojgan Moghaddassi, Pharm D
Manager
US Regulatory Affairs

August 13, 2004

Anuja M. Patel, M.P.H.
Advisors and Consultants Staff
FDA, CDER, OEP
HFD-21, Room 1093
5630 Fishers Lane
Rockville, MD 20852-1734

RE: NDA 19-839 & NDA 20-990*
ZOLOFT® (SERTRALINE HYDROCHLORIDE) TABLETS & ORAL CONCENTRATE
BACKGROUND PACKAGE FOR SEPTEMBER 13-14, 2004 ADVISORY COMMITTEE

Dear Ms. Patel,

With this amendment we are submitting 60 additional hard copies of the cover letter that was submitted with our background package on August 10, 2004.

If you have any questions, please do not hesitate to contact me at (212) 733-3332.

Sincerely,

A handwritten signature in cursive script that reads "Mojgan Moghaddassi".

Mojgan Moghaddassi, Pharm D

cc: Mr. Paul David, FDA/CDER/OND/DNDP (HFD-120) (cover letter only)

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Dear Ms. Patel:

Reference is made to the Division's letter dated June 24 2004, and Pfizer's response on July 6 2004, concerning the submission of a background package for the upcoming joint meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and Pediatric Advisory Committee (PAC) which will be held on September 13 and 14, 2004.

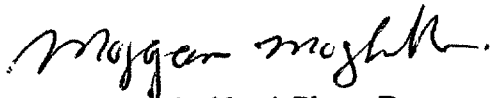
With this response, Pfizer is submitting information that it considers relevant to the evaluation that is being conducted by the FDA. Portions of the information contained in the package are of a background nature, which Pfizer considers relevant and essential, particularly given that some members of the Pediatric Advisory Committee may not be fully aware of the epidemiology, symptoms and seriousness of major depressive disorder as a public health problem in the pediatric population.

In addition, Pfizer is providing a copy of our response to an open letter by Dr. David Healy to Peter J. Pitts, Associate Commissioner for External Relations, FDA, purportedly in response to issues not addressed at the February 2, 2004 PDAC meeting regarding SSRIs. Dr. Healy's letter, which is posted on the Alliance for Human Research Protection website, is rife with erroneous statements, unsupported contentions and data distortions and Pfizer believes it is critical that the record be appropriately corrected. Pfizer's response to Dr. Healy's letter was also sent to Drs. Temple, Katz and Laughren on July 26, 2004, and is provided under tab 2. Dr. Healy's original letter is provided under tab 3.

As per the instructions given to Pfizer, 60 hard copies and 2 electronic copies (in Microsoft Word) of our fully releasable background package are provided.

If you have any questions, please do not hesitate to contact me at (212) 733-3332.

Sincerely,



Mojgan Moghaddassi, Pharm D

cc: Mr. Paul David, FDA/CDER/OND/DNDP (HFD-120) (cover letter only)