DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-031 / S-059
NDA 20-710 / S-023
NDA 20-936 / S-035

GlaxoSmithKline
Attn: Randal Batenhorst, BS Pharm, Pharm.D.
Vice President, US Regulatory Affairs - Neurosciences
5 Moore Drive
Research Triangle Park, NC 27709-3398

Dear Dr. Batenhorst:

Please refer to your supplemental new drug applications referenced above, which were dated March 11, 2008, received March 12, 2008, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil® (paroxetine hydrochloride) Tablets [NDA 20-031 / S-059], Paxil® (paroxetine hydrochloride) Oral Suspension [NDA 20-710 / S-023], and Paxil CR® (paroxetine hydrochloride) Controlled-Release Tablets [NDA 20-936 / S-035], respectively.

We also acknowledge receipt of your submissions, made simultaneously to all three supplemental applications, dated March 6, 2009.

These supplemental new drug applications provide for updates of the existing section "Usage in Pregnancy: Teratogenic Effects" in the Paxil and Paxil CR labeling to reflect data from two recently published articles by Louik et al. and Alwan et al. on "First Trimester Use of Selective Serotonin Reuptake Inhibitors and the Risk of Birth Defects".

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

Final Printed Labeling. The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l) in Structured Product Labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit this version to the National Library of Medicine for public dissemination. For administrative purposes, please clearly label this submission as **"SPL for Approved NDA 20-031 / S-059, NDA 20-710 / S-023, and NDA 20-936 / S-035".**

If you issue a letter communicating important information about these drug products (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to the respective NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Doris J. Bates, Ph.D., Senior Regulatory Project Manager, at (301) 796-2260, or email her at doris.bates@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Approved Agreed-Upon Labeling
NDA 20-031 / S-059
NDA 20-710 / S-023
NDA 20-936 / S-035

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MITCHELL V Mathis
08/07/2009
For Dr. Laughren