DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-031/S-060
NDA 20-936/S-037
NDA 20-710/S-024

GlaxoSmithKline
Attention: Barbara E. Arning, M.D.
Senior Director, US Regulatory Affairs
2301 Renaissance Blvd.
King of Prussia, PA 19606-2772

Dear Dr. Arning:

Please refer to your supplemental new drug applications dated and received June 6, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Paxil (paroxetine HCl) tablets (NDA 20-031), Paxil CR (paroxetine HCl) Controlled-Release tablets (NDA 20-936), Paxil (paroxetine HCl) oral suspension (NDA 20-710).

We also refer to your amendment submitted June 13, 2008 to include the discontinuation paragraph which was previously omitted in labeling.

These "Changes Being Effected" supplemental new drug applications provide for additions to the **PRECAUTIONS-Drug Interactions: Drug Metabolized by CYP2D6** Section of the labeling regarding an interaction between paroxetine and tamoxifen.

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

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplements NDAs 20-031/S-060, NDA 20-936/S-037, and NDA 20-710/S-024".

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, call Renmeet Grewal, Pharm.D., Senior Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling

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

/s/

Thomas Laughren
10/31/2008 09:16:16 AM