DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDAs 020031/S-063, 020710/S-027, 020936/S-041

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Randall Batenhorst, Pharm.D.
Vice President
U.S. Regulatory Affairs
5 Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Batenhorst:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received July 21, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PAXIL (paroxetine HCl) 10mg, 20mg, 30mg, 40mg tablets; PAXIL 10mg/5mL oral solution; and PAXIL CR 12.5mg, 25mg, 37.5mg tablets.

We acknowledge receipt of your amendments dated July 30, 2010 and September 27, 2010.

These Prior Approval supplemental new drug applications provide for an update to U.S. prescribing information with respect to the following safety concerns:

- Bone fracture (in PRECAUTIONS)
- Interaction with fentanyl (in PRECAUTIONS/Drug Interactions/Serotonergic Drugs)
- Male fertility (in PRECAUTIONS/Carcinogenesis, Mutagenesis, Impairment of Fertility)
- Restless legs syndrome (in ADVERSE REACTIONS/Postmarketing Reports)
- Use of gastric lavage and activated charcoal to manage overdosage (in Overdosage/Overdosage Management)

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text and with the minor editorial revision listed below and included in the enclosed labeling.

- The phrase “and exchange transfusion” in the Overdosage/Overdosage Management section was updated to the agreed upon language, “or exchange perfusion”

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to, except with the revisions indicated, the enclosed labeling (text for the package insert and Medication Guide) and include the labeling changes proposed in any pending “Changes

Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days from the date of this letter, amend all pending supplemental applications for this NDA, including pending CBE supplements, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes with the revisions indicated above approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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, email your Regulatory Project Manager at Juliette.Toure@fda.hhs.gov.

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

ENCLOSURES:
Content of Labeling for:

- PAXIL (paroxetine HCl) tablets and oral solution
- PAXIL CR tablets

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

/s/

THOMAS P LAUGHREN
10/27/2010