DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20031/S-067
NDA 20710/S-031
NDA 20936/S-045

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Eric B. Benson
Senior Director, US Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Benson:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received October 22, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Paxil (paroxetine HCl) 10mg, 20mg, 30mg, 40mg tablets (NDA 020031/S-067), Paxil 10mg/5mL oral solution (NDA 020710/S-031), and Paxil CR 12.5mg, 25mg, 37.5mg controlled-release tablets (NDA 020936/S-045).

We acknowledge receipt of your amendments dated August 15, 2011, August 15, 2012, and October 2, 2012.

The August 15, 2011 submission constituted a complete response to our July 29, 2011 action letter.

These "Prior Approval" supplemental new drug applications provide for class labeling revisions to the **Contraindications**, **Warnings, Precautions**, and **Dosage and Administration** sections and Medication Guide regarding serotonin toxicity associated with the co-administration of linezolid and methylene blue as well as revisions related to persistent pulmonary hypertension of the newborn which was provided to you in the March 8, 2012, June 26, 2012, July 31, 2012, September 5, 2012 email correspondence.

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.

We note that your October 2, 2012, submission includes final printed labeling (FPL) for your package insert and Medication Guide. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Juliette Touré, PharmD, Senior Regulatory Project Manager, at Juliette.Toure@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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
12/18/2012