DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020031/S-058/S-066
NDA 020710/S-022/S-030
NDA 020936/S-034/S-044

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 your Supplemental New Drug Applications (sNDA) dated August 31, 2007 (NDAs 020031/S-058, 020710/S-022, 020936/S-034), and October 8, 2010 (NDAs 020031/S-066, 020710/S-030, 020936/S-044),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), Paxil 10mg/5mL oral solution (NDA 020710), and Paxil CR 12.5mg, 25mg, 37.5mg controlled-release tablets (NDA 020936).

We acknowledge receipt of your amendment dated June 29, 2011.

The June 29, 2011, submission constituted a complete response to our June 16, 2011, action letter.

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to product labeling:

020031/S-058, 020710/S-022, 020936/S-034

- Contraindication of the co-administration of paroxetine and the reversible non-selective monoamine oxidase inhibitor (MAOI) linezolid.

- Revision of the Drug Interactions section to add the pharmacological mechanism for increased pimozide levels when pimozide is co-administered with paroxetine.

020031/S-066, 020710/S-030, 020936/S-044

- Addition of methylthioninium chloride (methylene blue) to the CONTRAINDICATIONS section of U.S. prescribing information as an example of an MAOI.

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 June 29, 2011, 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).

Additionally, please note that although we have incorporated revisions proposed in your "Changes Being Effected" supplements dated October 22, 2010 (20031/S-067, 20710/S-031, & 20936/S-045), and November 9, 2010 (20031/S-068, 20710/S-032, & 20936/S-046), these supplements are currently under review.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications

5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 Juliette Touré, PharmD, Senior 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

Enclosure: 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/

THOMAS P LAUGHREN
07/08/2011