DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020031/S-062/S-065/S-069
NDA 020710/S-026/S-029/S-033
NDA, 020936/S-040/S-043

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 the following Supplemental New Drug Applications (sNDA) 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 controlled-release tablets:

- Prior Approval Labeling Supplements 020031/S-069, 020710/S-033, dated and received January 21, 2011. These supplements provide for the addition of the following statement to the CLINICAL PHARMACOLOGY section, Pharmacokinetics subsection, per our Prior Approval Supplement request letter dated January 4, 2011.

  In a meta-analysis of paroxetine from 4 studies done in healthy volunteers following multiple dosing of 20 mg/day to 40 mg/day, males did not exhibit a significantly lower Cmax or AUC than females.

- Changes Being Effected Labeling Supplements 020031/S-065, 020710/S-029, 020936/S-043, dated and received June 16, 2010. These supplements provides for an update to the tamoxifen drug interaction in the Precautions section.

- Prior Approval Labeling Supplements 020031/S-062, 020710/S-026, 020936/S-040, dated and received May 15, 2009. These supplements provide for a comprehensive medication guide, per our Prior Approval Supplement request letter dated April 16, 2009.

We acknowledge receipt of your amendments dated and received March 26, 2010, November 12, 2010, and February 7, 2011.

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 March 16, 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 August 31, 2007 (20031/S-058, 20710/S-022, & 20936/S-034), October 8, 2010 (20031/S-066, 20710/S-030, & 20936/S-044), 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 (package insert and Medication Guide)

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
03/21/2011