DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18644/S-042
NDA 20358/S-039/S-049

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Mary E. Martinson
Senior Director, Psychiatry, US Regulatory Affairs
P.O. Box 13398, Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Ms. Martinson:

Please refer to your Supplemental New Drug Applications (sNDA) dated September 10, 2010 (18644/S-042 and 20358/S-049), and January 31, 2006 (20358/S-039), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Wellbutrin (bupropion hydrochloride) 75 mg and 100 mg Tablets (NDA 18644) and Wellbutrin SR (bupropion hydrochloride) Sustained-Release 100 mg, 150 mg, and 200 mg Tablets (NDA 20358).

We additionally acknowledge receipt of your amendments dated February 27, 2009, July 12, 2010, March 4, 2011, March 7, 2011, April 15, 2011, and May 5, 2011.

Your February 27, 2009, submission constituted a complete response to our January 29, 2007 action letter for supplemental application 20358/S-039.

These supplemental new drug applications provide for the following changes to product labeling:

NDA 20358/S-039 submitted as a "Prior Approval" supplement

- Revisions to the **CLINICAL PHARMACOLOGY: Pharmacokinetics: Absorption** and **PATIENT INFORMATION** sections based upon a food effect study

NDAs 18644/S-042 & 20358/S-049 submitted as a "Prior Approval" supplement

- Revisions to **CLINICAL PHARMACOLOGY: Metabolism** and **PRECAUTIONS: Drug Interactions** – Addition of pharmacokinetic information from a study of healthy volunteers taking efavirenz and bupropion.
- Revisions to **PRECAUTIONS: Drug Interactions**- Statement deleted as a number of drug interaction studies have been conducted providing data on the metabolism of bupropion following concomitant administration of other drugs or the effect of concomitant administration of bupropion on the metabolism of other drugs.

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

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), 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}

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
05/17/2011