DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18644/S-043
NDA 20358/S-050

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 May 17, 2011, 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 amendment dated June 14, 2011.

Reference is also made to an Agency letter dated April 20, 2011, requesting revisions to the Wellbutrin and Wellbutrin SR labelings.

These supplemental new drug applications, submitted as "Prior Approval" labeling supplements, provide for the following changes as requested in our April 20, 2011 letter:

- The addition of the following new subsection under the **Precautions** section entitled **Drug Laboratory Test Interactions** as requested

  Drug-Laboratory Test Interactions

  False-positive urine immunoassay screening tests for amphetamines have been reported in patients taking bupropion. This is due to lack of specificity of some screening tests. False-positive test results may result even following discontinuation of bupropion therapy. Confirmatory tests, such as gas chromatography/mass spectrometry, will distinguish bupropion from amphetamines.

- Corollary changes to the Medication Guide regarding false positive test results for amphetamines.

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/

MITCHELL V Mathis
07/25/2011
For Dr. Laughren