DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020711/S-031

SUPPLEMENT APPROVAL

SmithKline Beecham Corporation
d/b/a GlaxoSmithKline
5 Moore Drive
Research Triangle Park, NC 27709

Attention: Mary E. Martinson
Senior Director, Psychiatry
U.S. Regulatory Affairs

Dear Ms. Martinson:

Please refer to your supplemental new drug application dated December 3, 2008, received December 3, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyban (bupropion hydrochloride) Sustained-Release Tablets 100 mg and 150 mg.

We acknowledge receipt of your amendment dated July 22, 2010.

This "Prior Approval" supplemental new drug application proposes revisions to the following sections of the product labeling:

1. **CLINICAL PHARMACOLOGY: Metabolism** and **PRECAUTIONS: Drug Interactions**- Addition of pharmacokinetic information from a series of studies concerning drug interactions between bupropion and ritonavir and lopinavir/ritonavir.

2. **PRECAUTIONS: Drug Interactions**- Addition of ticlopidine and clopidogrel as examples of drugs that are substrates of or inhibitors/inducers of CYP2B6 and thus may interact with bupropion. Addition of statement that bupropion increases the C_{max} and AUC of citalopram by 30% and 40%, respectively.

3. **DOSAGE AND ADMINISTRATION** and the **Medication Guide -** An update to the statement "Do not chew, divide, or crush tablets" to add "as this may lead to an increased risk of adverse effects, including seizures".

4. **MEDICATION GUIDE:** Addition of the statement "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088", as required by FDA Final Rule issued October 28, 2008, Toll Free Number for Reporting Adverse Events on Labeling for Human Drug Products.

5. Minor editorial changes

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling text for the patient package insert, Medication Guide and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 pending "Changes Being Effected" (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.

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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and 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, contact Ayanna Augustus, Regulatory Project Manager, at ayanna.augustus@fda.hhs.gov or (301) 796-3980.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D.
Deputy Director of Safety
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
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/

LARISSA LAPTEVA
09/20/2010