DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 020711/S-034

APPROVAL LETTER

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 and received April 16, 2009, 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 submission dated November 23, 2009.

This supplemental new drug application provides for a Risk Evaluation and Mitigation Strategy (REMS) for Zyban (bupropion hydrochloride). The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the FDCA authorizes FDA to require the submission of a REMS if FDA becomes aware of new safety information and makes a determination that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks (section 505-1(a)).

Since Zyban (bupropion hydrochloride) was approved on May 14, 1997, for the treatment of smoking cessation, we have become aware of adverse reports of suicidality-related events in patients using Zyban. We consider this information to be "new safety information" as defined in section 505-1(b) of FDCA.

Your proposed REMS, submitted on November 23, 2009, and appended to this letter, is approved. The REMS consists of a Medication Guide and the timetable for submission of assessments of the REMS.

The REMS assessment plan should include an evaluation of patients' understanding of the serious risks of Zyban.

The requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(B) and (C), information on the status of any post-approval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. You can satisfy these requirements in your REMS assessments by referring to relevant information

included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in 505-1(g) could result in enforcement action.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in Section 505-1(g)(2)(A) of FDCA.

Prominently identify the submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 020711 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 020711
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 020711
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions. We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 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}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia, and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:

1. REMS
2. Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20711	SUPPL-34	GLAXOSMITHKLINE	ZYBAN

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
02/26/2010
for Bob Rappaport, M.D.