DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-711/S-024

GlaxoSmithKline
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

Attention: Mary E. Martinson
Director, Psychiatry US Regulatory Affairs

Dear Ms. Martinson:

Please refer to your supplemental new drug application dated October 27, 2005, received October 28, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyban® (bupropion hydrochloride) Sustained-Release Tablets.

This "Changes Being Effected" supplemental new drug application provides for changes in the product labeling for Zyban and for unbranded bupropion hydrochloride sustained-release tablets regarding container labeling and the inclusion of the Medication Guide for unit-of-use packaging presentations.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 27, 2005.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Dominic Chiapperino, Regulatory Project Manager, at (301) 796-1183.

Sincerely,

{See appended electronic signature page}

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Celia Winchell
4/28/2006 05:38:49 PM
for Bob A. Rappaport, M.D., Division Director