



NDA 20-711/S-022

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 August 30, 2005, received August 31, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyban® (bupropion hydrochloride) Sustained-Release Tablets.

We additionally acknowledge receipt of your submitted amendment dated October 28, 2005, received October 31, 2005, providing Final Printed Labeling (FPL).

This "Changes Being Effectuated" supplemental new drug application provides for additions to the **Warnings to Physicians-Clinical Worsening and Suicide Risk** section based upon APA guidelines.

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 28, 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/

-----  
Rigoberto Roca  
3/13/2006 03:49:25 PM  
for Bob Rappaport, M.D.