DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-644/S-033/S-034
NDA 20-358/S-037/S-040
NDA 21-515/S-014

GlaxoSmithKline
Attention: Mary E. Martinson
Director, Psychiatry US Regulatory Affairs
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Martinson:

We acknowledge receipt of your supplemental new drug applications for Wellbutrin Immediate Release Tablets (NDA 18-644), Wellbutrin SR (bupropion hydrochloride) Sustained-Release Tablets (NDA 20-358), and Wellbutrin XL (bupropion hydrochloride) Extended-Release Tablets (NDA 21-515).

These "Changes Being Effected" supplemental new drug applications provide for the following revisions to product labeling:

NDA 18-644/S-033 dated December 21, 2005
NDA 20-358/S-037 dated October 26, 2005
NDA 21-515/S-014 dated October 18, 2005

- These supplements to the IR, SR, and XL formulations provide for a larger and more prominent font to state the number of times a day the bupropion formulation should be taken. This was changed to address the potential for confusion among different modified-release bupropion products.

NDA 18-644/S-034 dated May 16, 2006
NDA 20-358/S-040 dated May 16, 2006

- These supplements provide for revisions to the **PRECAUTIONS-Pregnancy** section to change the pregnancy category from Pregnancy Category B to Pregnancy Category C.

We have completed our review of these supplemental new drug applications, as amended, They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 16, 2006 and attached to this letter (enclosure).

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 Dr. Renmeet Gujral, Regulatory Project Manager, at (301) 796-1080.

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

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

/s/

Thomas Laughren
7/3/2006 08:16:42 PM