DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-644 / S-035
NDA 20-358 / S-042

GlaxoSmithKline
Attention: Mary E. Martinson
US Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Martinson:

Please refer to your supplemental new drug applications dated and received September 26, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin (bupropion HCl) Tablets and Wellbutrin SR (bupropion HCl) Sustained-Release Tablets.

These "Changes Being Effected" supplements provide for the combination of the patient package insert and Medication Guide, as well as other changes in the product labeling as provided for in the June 12, 2006 approval of NDA 21-515, supplement 010, for Wellbutrin XL.

We have completed our review of these supplements and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 26, 2006 (marked-up copy attached).

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@FDA.HHS.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of New Drug Evaluation I
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/

Thomas Laughren
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