DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-358/S-030

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 application dated March 10, received March 11, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin SR (bupropion hydrochloride) Sustained-Release 100 mg, 150 mg, and 200 mg Tablets.

This "Changes Being Effected" supplemental new drug application proposes the addition of the phrase "twice a day" on container labeling along with a reference to full dosing information, i.e., "See package insert for dosage information".

We note that these changes were requested in an Agency letter dated August 28, 2003, to the Wellbutrin XL NDA, 21-515, to minimize the potential for confusion between the two products.

We have completed the review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed labeling submitted on March 10, 2004. Accordingly, the supplemental new drug application is approved effective on the date 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, call Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of 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/

Russell Katz
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