DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-515/S-002

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 November 4, 2003, received November 5, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin XL (bupropion hydrochloride) Extended-Release Tablets.

We additionally acknowledge receipt of your amendment dated March 15, 2004, received March 16, 2004.

This supplemental application, submitted as a "Prior Approval" labeling change, provides for the inclusion of additional bioequivalence data demonstrating the bioequivalence of Wellbutrin XL to the sustained-release formulation of bupropion HCl (Wellbutrin SR). The changes to the labeling are reflected in the **CLINICAL PHARMACOLOGY**, **CLINICAL TRIALS**, **WARNINGS**, and **ADVERSE REACTIONS** sections of labeling.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your November 4, 2003 labeling text. Accordingly, this application is approved effective on the date of this letter. Please be notified that the proposed labeling text (package insert) must incorporate the revisions approved in the Agency Letter dated May 27, 2004.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated November 4, 2003 with incorporated revisions reflected in the Agency Letter dated May 27, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-515/S-002." Approval of this submission by FDA is not required before the labeling is used.

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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