DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-644/S-026
NDA 20-358/S-029

Glaxo SmithKline
Attention: James Murray
Director Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Murray:

Please refer to your supplemental new drug applications dated April 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin (bupropion hydrochloride) 75 mg and 100 mg Immediate-Release Tablets (NDA 18-644) and Wellbutrin SR (bupropion hydrochloride) Sustained-Release 100 mg and 150 mg Tablets (NDA 20-358).

These "Changes Being Effected" supplemental new drug applications provide for revisions to the **CONTRAINDICATIONS**, **WARNINGS**, and **PRECAUTIONS** section of the prescriber labeling as well as revisions to the Patient Package Insert concerning alcohol and sedative use.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

We note that, although these applications provided for final printed labeling, they did not incorporate the agreed upon changes as stated in our approval letter dated June 20, 2002, for supplemental applications 18-644/S-022/S-023 & 20-358/S-018/S-023. Therefore, we are requesting that you again submit final printed labeling which incorporates all of the approved revisions to product labelings.

Please submit the copies of final printed labeling (FPL) electronically to each application 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, these submissions should be designated "FPL for approved supplements 18-644/S-022S-023/S-026 and 20-358/S-018/S-023/S-029". Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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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