



NDA 18-644/S-024

NDA 20-358/S-024

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

Dear Ms. Martinson:

Please refer to your supplemental new drug applications dated August 7, 2001, and received on August 8, 2001, 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).

We additionally refer to an Agency approvable letter dated April 16, 2002.

We acknowledge receipt of your complete responses dated August 21, 2002, to the above action letter.

Supplemental applications 18-644/S-024 & 20-358/S-024, submitted under "Changes Being Effected", provide for revisions to the patient package insert (PPI).

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 final printed labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

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 these NDAs 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
10/2/02 08:46:29 AM