NDA 20-358/S-019

Glaxo Wellcome 11 JUN 2001
Attention: James Murray
Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Murray:

Please refer to your supplemental new drug application dated May 31, 2000, received June 1, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin SR (bupropion hydrochloride) Sustained-Release 100 mg and 150 mg Tablets.

We acknowledge receipt of your submission dated March 27, 2001. Your submission of March 27, 2001 constituted a complete response to our February 26, 2001 action letter.

This supplemental new drug application proposes the use of Wellbutrin SR in maintaining an antidepressant effect when dosed up to one year, and provides for changes to the **CLINICAL PHARMACOLOGY-Clinical Trials**, **INDICATIONS AND USAGE**, and **DOSAGE AND ADMINISTRATION-Maintenance Treatment** sections of labeling.

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 27, 2001 (Label Code RL-917). Accordingly, the supplemental new drug application is approved effective on the date of this letter.

Additionally, we note that the final printed labeling submitted on March 27, 2001, only incorporates the changes requested in our Agency letter dated February 26, 2001 when compared to the last approved labeling revision (20-358/S-015; approval date April 10, 2000; Label Code RL-750). Please note that pending supplemental applications 20-358/S-018/S-023 are still under review by the Agency.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research