DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-358/S-027

GlaxoWellcome Inc.
Attn: Leo Lucisano, R. Ph.
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Lucisano:

Please refer to your supplemental new drug application dated February 15, 2002, received February 19, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin SR® (bupropion hydrochloride) Tablets.

We also acknowledge receipt of your submission dated April 1, 2002.

This supplemental application provides for the use of a new 200 mg strength Wellbutrin SR tablet as an additional dosage strength. It includes the results of a bioequivalence study comparing the new 200 mg tablet to the currently marketed 100 mg tablet. In addition, the supplement includes proposed labeling (package insert, patient package insert, and container labeling) relevant to the new 200 mg strength.

We have completed our review of this supplemental application and it is approved, subject to the following comments:

Chemistry, Manufacturing, and Controls

We are approving this supplement with an 18 month expiration date for the drug product.

We also note the following approved dissolution specification for the 200 mg tablet:

Apparatus:	USP Apparatus II (Paddle) at 50 RPM	
Medium:	900 mL of water at 37±0.5°C	
Specifications:	at 1 hour:	25 – 45% of labeled strength released
	at 4 hours:	60 – 85% of labeled strength released
	at 8 hours:	NLT 80% of labeled strength released

Request for Submission of Final Printed Labeling (FPL)

We are approving this supplement based upon your submitted proposed labeling (package insert with Patient Package Insert). A clean copy of this labeling is provided as an attachment to this letter. The final printed labeling (FPL) must be identical to the enclosed labeling text and to the immediate container and carton labels as submitted on February 15, 2002.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded, and thus an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA.* 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. Individually mount ten of the paper copies on heavy-weight paper or similar material. For administrative purposes, please designate these submissions "FPL for approved supplemental NDA 20-358/S-027". Approval of this labeling submission by FDA is not required before the labeling is used.

Communicating Important Information About this Drug Product

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

You are reminded that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you should have any questions, please contact Doris J. Bates, Ph.D., Regulatory Project Manager, at 301.594.5536.

Sincerely yours,

[see electronic signature page]

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

Attachment: electronic copy of agreed upon labeling test (package insert and PPI)

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
6/14/02 09:29:55 AM