CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
20-358/S020/S021/S022

Trade Name: Wellbutrin SR Tablets, 100 mg

Generic Name: (bupropion hydrochloride)

Sponsor: GlaxoWellcome Inc.

Approval Date: October 11, 2000

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APPROVAL LETTER

20-358/S020/S021/S022

43-1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-358/S-020, S-021, S-022

GlaxoWellcome Inc.
Attn: Greg Hileman, PhD
Five Moore Drive
Research Triangle Park, NC 27709

OCT 11 2000

Dear Dr. Hileman:

Please refer to your supplemental new drug applications dated June 13, 2000, received June 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Wellbutrin SR® (bupropion hydrochloride) Tablets, 100 mg.

We also acknowledge receipt of your submissions dated August 29, 2000 and September 21, 2000.

The supplemental applications propose the following changes which affect only the 100 mg SR tablet:

- A modified tablet composition
- An updated manufacturing process including revised in-process controls
- A new manufacturing site (Zebulon, NC), which will perform manufacturing, packaging, and labeling operations
- A new container/closure system
- Updated regulatory specifications for impurities and product appearance
- Modified analytical methods for Identification, Content Uniformity, Drug Release, Content, and Impurities
- Stability data, with a request for an 18 month expiration date

The supplements also include the results of a bioequivalence study comparing the reformulated 100 mg SR tablet to the currently marketed product.

We have completed our review of these supplemental applications and they are approved, subject to the following comment:

Chemistry, Manufacturing, and Controls

We are approving this supplement with a tentative 18 months expiration date for the drug product. This tentative date must be confirmed via the submission of real-time data to the NDA Annual Report.

We also note that you plan to revise the container labeling for this product to indicate that the product appearance (tablet size) has changed. We agree to your proposal to use the revised labeling for one year, then remove the size change alert. Labeling with the alert deleted will then be submitted in the next applicable Annual Report for this NDA.

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,

10/11/00

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

CC:
Archival NDA 20-358 / S-020, -021, -022
HFD-120/Division File
HFD-120/RKatz
HFD-120/TLaughren
HFD-120/DJBates
HFD-810/Rseevers/CJohn
HFD-860/RBaweja/HZhao
DISTRICT OFFICE

10-10-00

Drafted by: djb/rhs/04OCT00
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Final:

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APPROVAL (AP)