

**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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RESEARCH**

**APPROVAL LETTER**

**20-358/S020/S021/S022**

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**

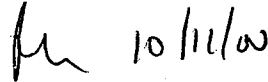
We are approving this supplement with a tentative 18 months expiration date for the drug product. This tentative date must be confirmed via the submission of real-time data to the NDA Annual Report.

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,

Handwritten signature of Russell Katz, dated 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

*WZ* 10-10-00

Drafted by: djb/rhs/04OCT00

Initialed by: see above

Final:

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APPROVAL (AP)