

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number: NDA 20-711**

**APPROVAL LETTER**

NDA 20-711

Food and Drug Administration  
Rockville MD 20857

MAY 14 1997

Glaxo Wellcome Inc.  
Five Moore Drive  
Research Triangle Park, North Carolina 27709

Attention: Eric B. Benson  
Product Director  
Regulatory Affairs

Dear Mr. Benson:

Please refer to your new drug application (NDA) dated May 17, 1996, received June 3, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyban (bupropion hydrochloride sustained-release tablets), 100 mg and 150 mg.

We acknowledge receipt of your submissions dated May 23, June 12, 13, 18 and 28, July 23 and 29, August 1, 2, 15, and 29, October 3, 11, and 16, November 5, 8, and 18, December 4 and 20, 1996; February 14 and 21, March 17 and 25, April 18, 23 and 28, and May 1, 1997. The User Fee goal date for this application is June 3, 1997.

This new drug application provides for bupropion to be used as an aid to smoking cessation treatment.

We have completed the review of this application, including the submitted draft labeling, 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 enclosed draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-711. Approval of this submission by FDA is not required before the labeling is used.

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Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material 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 material and the package insert directly to:

Food and Drug Administration  
Division of Drug Marketing, Advertising and Communications,  
HFD-40  
5600 Fishers Lane  
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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, please contact Bonnie McNeal, Project Manager, at (301) 443-3741.

Sincerely,

Curtis Wright, M.D., M.P.H.  
Acting Director  
Division of Anesthetic, Critical Care, and  
Addiction Drug Products, HFD-170  
Office of Drug Evaluation III  
Center for Drug Evaluation and Research

ENCLOSURE

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cc:

Original NDA 20-711

HFD-170/Div. files

HFD-170/CSO/B.McNeal/CMoody

HFD-170/CWinchell/MScheinbaum/CLi/PMaturu/BHayes/PLockwood/JMa

HFD-002/ORM (with labeling)

HFD-103/Office Director

HFD-101/L.Carter

HFD-820/ONDC Division Director

DISTRICT OFFICE

HF-2/Medwatch (with labeling)

HFD-92/DDM-DIAB (with labeling)

HFD-40/DDMAC (with labeling)

HFD-613/OGD (with labeling)

HFD-735/DPE (with labeling) - for all NDAs and supplements for adverse reaction changes.

HFI-20/Press Office (with labeling)

HFD-021/ACS (with labeling)

Final Draft Init. by:           Supervisory CSO \_\_\_\_\_  
  Supervisory MO \_\_\_\_\_  
  Supervisory Chem \_\_\_\_\_  
  Supervisory Pharm \_\_\_\_\_  
  Supervisory PK \_\_\_\_\_  
  Supervisory Stat. \_\_\_\_\_

Drafted by: Bmc/April 25, 1997/n20711.apr on N drive under cso/Bonnie

Initialed by: PMaturu 5/13; MScheinbaum 5/13; BHayes 5/13; SDoddapaneni 5/13;  
JMa 5/13/97; AD'Sa; CMoody 5/14/97.

final: BmcNeal 5/14/97

APPROVAL (AP)