

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**20-711/SE8-012**

**Approval Letter**



NDA 20-711/S-012

2/7/01

GlaxoWellcome Inc.  
Five Moore Drive  
Research Triangle Park, NC 27709

Attention: Eric Benson  
Director, Regulatory Affairs

Dear Mr. Benson:

Please refer to your supplemental new drug application dated April 26, 2000, received April 27, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyban (bupropion hydrochloride) Sustained-Release Tablets.

We acknowledge receipt of your submissions dated August 25, October 18, and November 20, 2000, and February 2, 2001.

This supplemental new drug application provides for the use of Zyban (bupropion hydrochloride) Sustained-Release Tablets in chronic obstructive pulmonary disease (COPD) patients, as an aid to smoking cessation.

We have completed the review of this supplemental application, as amended, 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 agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient information leaflet).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format- NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-711/S-012." Approval of this submission by FDA is not required before the labeling is used.

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.

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 send 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 you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7440.

Sincerely,

*{See appended ~~8~~ electronic signature page}*

Cynthia McCormick, M.D. -  
Director  
Division of Anesthetic, Critical Care, and  
Addiction Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

2/7/01

Enclosure: Text for package insert and text for patient information leaflet