CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020745

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-745

Glaxo Wellcome, Inc.
Attention: Sara Armentrout
Five Moore Drive
P.O. Box 13358
Research Triangle Park, NC 27709

JUL - 8 1997

Dear Ms. Armentrout:

Please refer to your new drug application dated July 2, 1996, received July 16, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for nonprescription Zantac® 75 EFFERdose® (ranitidine hydrochloride) Effervescent Tablets.

We acknowledge receipt of your submissions dated July 17; October 10 and 17; December 10, and 19, 1996; January 17; March 5; and April 22, 1997. The User Fee goal date for this application is July 16, 1997.

We have completed the review of this application as submitted with draft labeling, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) revised as follows:

A. Regarding all of the labeling for the drug product:

1. Revise the Statement of Identity from "Acid Reducer, Ranitidine Effervescent Tablets 75 mg" to "Ranitidine Effervescent Tablets 75 mg, Acid Reducer" to conform to 21 CFR 201.61(b).

2. Revise the word "BROKEN" to "TORN" in the Tamper Resistant/Tamper Evident Statement "DO NOT USE IF THE INDIVIDUAL FOIL POCKET IS OPEN OR BROKEN". In addition, if space allows, consider adding this statement to the foil pouch label.

B. Concerning the carton label, please confirm where the Lot Number and Expiration Date will be printed.

C. Regarding the package insert:

1. Revise the second sentence of the first bullet statement in the section titled "What is Zantac 75 EFFERdose?" from "One EFFERdose tablet dissolves quickly in water into a clear, easy-to-swallow liquid without the grit and gas of other effervescent heartburn remedies" to "One EFFERdose tablet dissolves in water into a clear liquid."

2. Revise the fourth bullet statement of the section titled "What is Zantac 75 EFFERdose?" from "Zantac 75 EFFERdose is a good choice for people who prefer a liquid medication, but do not want the inconvenience of bottled medicine away from home." to "Zantac 75 is an alternate choice for people who prefer a liquid medication but enjoy the convenience of traveling with a tablet" on all labeling.

3. Add the statement "This product should not be given to children under 12 years old unless directed by a doctor." to the end of the section entitled "How should I take Zantac 75 EFFERdose?".

4. Because the clinical efficacy study were actually conducted on the tablet formulation, revise the section entitled "Clinical studies prove Zantac 75 EFFERdose is effective" in the package insert to "Clinical Studies prove Zantac 75 is effective." and the header paragraph to "In clinical studies using Zantac 75 mg Tablets (of which Zantac 75 EFFERdose is equivalent), Zantac 75 was significantly better than placebo pills in relieving heartburn."

D. Regarding the pouch label, if space allows, consider adding the statements "Keep this and all drugs out of reach of children." and "Read the directions on carton, consumer leaflet, and warnings before use." to the label.

Please submit 20 copies of the printed labeling, ten of which are individually mounted on heavy-weight paper or similar material.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required. Additionally, if the February 27, 1997 Federal Register Notice "Over-the-Counter Human Drugs; Proposed Labeling Requirements" [62 FR 9023] becomes final before this application is approved, further revisions of the labeling format may be necessary.

In addition, please resubmit the Methods Validation package as a stand alone single volume document containing no cross references to other NDA volumes.

Please also 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

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action FDA may take action to withdraw the application.

The drug may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, please contact Michael Folkendt, Project Manager, at (301) 443-0487.

Sincerely yours,

/S/ 7-8-97

Lilia Talarico, M.D.
Acting Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

/S/ 07/07/97

Debra Bowen, M.D.
Division Director
Division of Over-The-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

cc:
Original NDA 20-745
HFD-180/Div. Files
HFD-002/ORM
HFD-92/DDM-DIAB
HFD-180/M.Folkendt
HFD-103/Office Director
HFD-101/L.Carter
DISTRICT OFFICE
HFD-40/DDMAC
HFD-560/OTC/S.Walther

APPEARS THIS WAY
ON ORIGINAL

Drafted by: mf/June 25, 1997
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APPROVABLE (AE)