CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020007/S022

APPROVABLE LETTER

NDA 20-007/S-022

GlaxoWellcome Inc.
Attention: George Phillips, Pharm.D.
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

MAY - 6 1997

Dear Dr. Phillips:

Please refer to your supplemental new drug application dated May 6, 1996, received May 7, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zofran (ondansetron HCl) Injection.

We acknowledge receipt of your submissions dated July 19 and 22, August 22, and December 18, 1996. The User Fee goal date for this application is May 7, 1997.

The supplemental application provides for intramuscular administration as an alternative to intravenous administration in the prevention of postoperative nausea and vomiting.

We have completed the review of this supplemental 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), identical in content to that submitted on December 18, 1996, with the Pharmacodynamics subsection of the CLINICAL PHARMACOLOGY modified as follows:

1. Revise the first paragraph proposed for inclusion to state:

   "In a gender-balance pharmacodynamic study (n=56), ondansetron 4 mg administered intravenously and intramuscularly was dynamically similar in the prevention of emesis and nausea using the ipecacuanha model of emesis. Both treatments were well tolerated.

2. With regard to the second paragraph proposed for inclusion, clarify why results from Study W91-016 (Bioavailability of IM Ondansetron 4 mg) were included in the labeling when Study S3AA1001 (A Study to Compare the Efficacy of 4 mg Ondansetron Intramuscular and 4 mg Ondansetron Intravenous in the Ipecacuanha Model of Emesis in Healthy Male and Female Volunteers) was submitted as the basis for approval of this supplement.

In addition, all previous revisions as reflected in the most recently approved package insert must be included.

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.

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

Within 10 days after the date of this letter, you are required to amend the supplemental 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.

This change may not be implemented until you have been notified in writing that this supplemental application is approved.

If you have any questions, please contact Kati Johnson, Supervisory Consumer Safety Officer, at (301) 443-0487.

Sincerely yours,

/S/ 5-5-97

APPEARS THIS WAY
ON ORIGINAL

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

cc:

Original NDA 20-007/S-022
HFD-180/Div. Files
HFD-002/ORM
HFD-103/Office Director
HFD-101/L.Carter
HFD-92/DDM-DIAB
HFD-40/DDMAC (with draft labeling)
DISTRICT OFFICE
HFD-180/CSO/K.Johnson
HFD-180/RPradhan

/S/ 5/5/97

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Drafted by: kj/May 5, 1997/c:\wpfiles\cso\n\20007705.s22

APPROVABLE (AE)

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