CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: 020007/S022

APPROVAL LETTER

Johnson

NDA 20-007/S-022
NDA 20-403/S-005

OCT 31 [illegible]

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

Dear Dr. Phillips:

Please refer to your supplemental new drug applications dated May 6, 1996 and July 25, 1997, received May 7, 1997 and July 28, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zofran (ondansetron HCL) Injection and Zofran (ondansetron HCL) Injection Premixed.

We acknowledge receipt of your submission dated July 25, 1997 to NDA 20-007/S-022, containing final printed labeling in response to our May 6, 1997 approvable letter. The User Fee goal date for NDA 20-007/S-022 is January 28, 1998.

The supplemental application NDA 20-007/S-022 provides for intramuscular administration as an alternative to intravenous administration in the prevention of postoperative nausea and vomiting. The supplemental (labeling) application NDA 20-403/S-005 was necessitated since the formulations share a common package insert.

We have completed the review of these supplemental applications including the submitted labeling and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the labeling in the submissions dated July 25, 1997 with the revisions listed below. Accordingly, the supplemental applications are approved effective on the date of this letter. The revisions required to the CLINICAL PHARMACOLOGY section are as follows:

1. Revise the number of patients included in the description of Study S3AA1001 from "28" to "56".
2. Revise the pharmacokinetic values listed for Study S3AA1001 to include the 95% confidence interval to indicate the variability of the parameter estimates.

These revisions are terms of the supplemental NDA approval.

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 supplemental NDAs 20-007/S-022, 20-403/S-005. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drugs 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 these products. 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 inserts directly to:

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

Should a letter communicating important information about these drug products (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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 Kati Johnson, Supervisory Consumer Safety Officer, at (301) 443-0487.

Sincerely yours,

/S/ 10-30-97

APPEARS THIS WAY
ON ORIGINAL

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

APPEARS THIS WAY
ON ORIGINAL

cc:
Original NDAs 20-007/S-022, 20-403/S-005
HFD-180/Div. files
HFD-180/CSO/K.Johnson
HFD-002/ORM (with labeling)
HFD-103/Office Director
HFD-101/L.Carter
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFI-20/Press Office (with labeling)

10/30/97

Drafted by: kj/October 30, 1997/c:\wpfiles\cso\n\20007s22.0kj

APPROVAL (AP)

APPEARS THIS WAY
ON ORIGINAL

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.