DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-781

GlaxoWellcome Inc.
Attention: Craig Metz, PhD
Director, Regulatory Affairs
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709

JAN 27 1999

Dear Dr. Metz:

Please refer to your new drug application (NDA) dated July 1, 1997, received July 2, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zofran ODT (ondansetron) Orally Disintegrating Tablets.

We acknowledge receipt of your submissions dated July 6, 8, 24, and 31, December 4, 1998, and January 7, 1999.

This new drug application provides for the use of Zofran ODT (ondansetron) Orally Disintegrating Tablets for the following indications: prevention of chemotherapy and radiation-induced nausea and vomiting, and prevention of postoperative nausea and vomiting.

We have completed the review of this 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 submitted labeling (package insert submitted July 31, 1998, immediate container and carton labels submitted July 31, 1998) with the revisions listed below. Accordingly, the application is approved effective on the date of this letter.

1. Modify the ADVERSE EVENTS section to replace the sentence, "The adverse experience profile seen with Zofran ODT Orally Disintegrating Tablets was similar to that seen with Zofran Tablets." with "Preliminary observations in a small number of subjects suggest a higher incidence of headache when Zofran ODT Orally Disintegrating Tablets are taken with water, when compared to without water."
2. Revise the following sentence in the PHARMACOKINETICS section to read, "Four and 8 mg doses of either ZOFRAN Oral Solution or ZOFRAN ODT Orally Disintegrating Tablets are bioequivalent to corresponding doses of ZOFRAN Tablets and may be used interchangeable."

These revisions are terms of the NDA approval. Marketing the product before making the revisions, exactly as requested, in the product's final printed labeling (FPL) 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 "FPL for approved NDA 20-781." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

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 submit 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-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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.

If you have any questions, contact Kati Johnson, Consumer Safety Officer, at (301) 827-7310.

Sincerely,

/S/

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