DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-103/S-018
NDA 20-605/S-005
NDA 20-781/S-002

DEC 13 2000

Glaxo Wellcome Inc.
Attention: Craig A. Metz, Ph.D.
Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Metz:

Please refer to your supplemental new drug applications dated December 22, 1999, received December 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zofran (ondansetron) Tablets, Oral Solution, and Zofran ODT Orally Disintegrating Tablets, respectively.

We acknowledge receipt of your submission dated October 4, 2000. Your submission of October 4, 2000 constituted a complete response to our August 4, 2000 action letter.

These "Changes Being Effected" supplemental new drug applications provide for the following changes to the package insert:

1. Addition of a Geriatric Use subsection in the PRECAUTIONS section, in accordance with 21 CFR 201.57(f)(1)(ii)(B), and

2. Modification to the CLINICAL PHARMACOLOGY and DOSAGE AND ADMINISTRATION sections, in accordance with 21 CFR 201.57(f)(10)(iii)(A).

We have completed the review of these supplemental applications, as amended, 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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted October 4, 2000), with the following exception: Delete the word “stylized” from the description of the Zofran ODT 4 and 8 mg tablets in the HOW SUPPLIED section.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for

industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-103/S-018, 20-605/S-005, 20-781/S-002." Approval of these submissions 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 Practitioner" 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.

If you have any questions, call Melodi McNeil, Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

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