DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-103/SCS-024

GlaxoSmithKline
Attention: Kim Hughes
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Dear Ms. Hughes:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Zofran (ondansetron hydrochloride) Tablets, 8 mg

NDA Number: 20-103

Supplement number: #S-024

Date of supplement: October 19, 2004

Date of receipt: October 20, 2004

This supplemental application provides for the deletion of the "protect from light" and related statements from the label, cartons, and blisters.

Your application was filed on December 18, 2004 in accordance with 21 CFR 314.101(a). The user fee goal date is February 20, 2005.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed draft package insert, draft bottle label (30s), display and tablets carton (3s and 100 unit-dose), Blister printmat (3s and 100 unit-dose), foil label (1), and physician sample pack submitted October 19, 2004.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-103/S-024**". Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Dr. Betsy Scroggs, Regulatory Health Project Manager at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Liang Zhou, Ph.D.
Chemistry Team Leader for the
Division of Gastrointestinal and Coagulation Drug Products (HFD-180)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Liang Zhou

2/18/05 11:17:49 AM