DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-007/S-035

GlaxoSmithKline
Attention: Ms. Margaret Martin, US Regulatory Affairs, Oncology
2301 Renaissance Boulevard,
Building 510, P.O. Box 61540
Mail Code RN0210
King of Prussia, PA 19406-2772

Dear Ms. Martin:

Please refer to your supplemental new drug application dated September 28, 2004, received September 29, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zofran® (ondansetron hydrochloride) Injection, 2 mg/mL.

We also refer to you submissions submitted September 28, January 5, 2005, March 21, 2005, and March 25, 2005 facsimile submission.

This supplemental new drug application provides for updating the label with new pediatric information.

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 draft electronic package insert submitted via electronic mail March 25, 2005.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-007/S-035." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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}

Dr. Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Attachment (package insert)

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

/s/

Kathy Robie-Suh
3/25/05 04:48:17 PM
signing for Dr. Joyce Korvick