DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-007/S-039
NDA 20-403/S-016

GlaxoSmithKline
Attention: Sandra L. Bihary-Waltz
Director, Regulatory Affairs, Oncology
2301 Renaissance Boulevard
P. O. Box 61540
King of Prussia, PA 19406-2772

Dear Ms. Bihary-Waltz:

Please refer to your supplemental new drug application dated February 22, 2006, received February 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA 20-007/S-039	ZOFRAN® (ondansetron hydrochloride) Injection
NDA 20-403/S-016	ZOFRAN® (ondansetron hydrochloride) Injection Premixed

These "Changes Being Effected" supplemental new drug applications provide for revisions to the package insert (PI) affecting the 1) PRECAUTIONS section and the 2) ADVERSE REACTIONS section.

We completed our review of these applications. These applications are 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 labeling text for the package insert submitted February 22, 2006 (RL-2236 February 2006).

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 Betsy Scroggs, Regulatory Project Manager, at (301) 796-0991.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Joyce Korvick

8/22/2006 05:19:32 PM