



NDA 20-103/S-021
NDA 20-781/S-003

GlaxoSmithKline
Attention: Matthew Whitman
Associate Director, Regulatory Affairs
1250 S. Collegeville Rd.
P.O. Box 5089
Collegeville, PA 19426-0989

Dear Mr. Whitman:

Please refer to your supplemental new drug applications dated August 2, 2002, received August 5, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOFTRAN® (ondansetron hydrochloride) Tablets and ZOFTRAN ODT® (ondansetron) Orally Disintegrating Tablets.

Although these supplemental new drug applications were submitted as "Changes Being Effected in 30 days" supplements, they should be classified as "Changes Being Effected" supplemental new drug applications under 21 CFR 314.70(c)(2)(iii). These supplements provide for revised graphics for the sample packs for the 1 x 8mg blister card and 5 x 8mg blister carton for ZOFTRAN® Tablets and ZOFTRAN ODT® Orally Disintegrating Tablets. These changes were submitted to improve the legibility of the labeling and were submitted in response to our June 7, 2000 letter.

We completed our review of these supplemental new drug applications, They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 2, 2002.

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, 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.

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If you have any questions, call Brian Strongin, R.Ph., M.B.A., Regulatory Project Manager, at (301) 827-7473.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D.
Deputy Director
Division of Gastrointestinal and Coagulation
Drug Products, HFD-180
Office of Drug Evaluation III

**This is a representation of an electronic record that was signed electronically and
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/s/

Joyce Korvick
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