DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-090/S-050
NDA 19-593/S-038

Glaxo Group Limited d/b/a GlaxoSmithKline
Attn: Mr. Robert J. Bohinski, Associate Director
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Mr. Bohinski:

Please refer to your supplemental new drug applications dated January 11, 2006, received January 12, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NDA 19-090: ZANTAC® (ranitidine hydrochloride) Injection and NDA 19-593: ZANTAC® (ranitidine hydrochloride) Injection Premixed.

These "Changes Being Effected" supplemental new drug applications provide for a revised label to add or strengthen a contraindication, warning, precaution or adverse reaction.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter. However, with the next revision of this drug label please make the following changes as agreed upon on July 12, 2006:

1. Removal of the following paragraph from the **PRECAUTIONS** section:

   6. In patients such as the elderly, persons with chronic lung disease, diabetes, or the immunocompromised, there may be an increased risk of developing community acquired pneumonia. A large epidemiological study showed an increased risk of developing community acquired pneumonia in current users of H_2-receptor antagonists versus those who had stopped treatment, with an observed adjusted relative risk increase of 1.63 (95% CI, 1.07-2.48).

2. The addition of the following in the **ADVERSE REACTION** section:

   Respiratory: A large epidemiological study suggested an increased risk of developing pneumonia in current users of histamine-2-receptor antagonists (H_2RAs) compared to patients who had stopped H_2RA treatment, with an observed adjusted relative risk of 1.63 (95% CI, 1.07-2.48). However, a causal relationship between use of H_2RAs and pneumonia has not been established.

The final printed labeling (FPL) must be identical to the package insert submitted January 11, 2006 with the addition of the revisions indicated above. These revisions are terms of the approval of this application.

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 19-090/S-050**" for example. 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please submit one market package of the drug product when it is available.

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 Giuseppe Randazzo, Regulatory Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

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

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

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