DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-675/S-030

GlaxoSmithKline
Attention: Patricia N. Ricciarelli
Senior Project Manager, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Ricciarelli:

Please refer to your supplemental new drug application dated August 26, 2003, (received August 27, 2003), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zantac® (ranitidine HCl) Syrup, 15mg/ml.

We acknowledge receipt on January 07, 2004, of your submission dated January 06, 2004. This submission is a complete response to our Approvable letter, dated December 17, 2003.

This supplemental application, proposes to revise the commercial long-term stability protocol by: a) elimination of the weight loss determination and b) elimination of the 3, 6, 9, and 18 month time points.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul E. Levine, Jr., R.Ph., J.D., Regulatory Health Project Manager, at (301) 827-7310.

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

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/s/

Liang Zhou

4/30/04 09:00:32 AM