DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-703/S-067
NDA 19-675/S-034
NDA 20-251/S-018

GlaxoSmithKline
Attention: Robert J. Bohinski
Associate Director, US Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Mr. Bohinski:

Please refer to your supplemental new drug applications dated and received April 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZANTAC 150/300 (ranitidine hydrochloride) Tablets, USP (NDA 18-703/S-067), ZANTAC (ranitidine hydrochloride) Syrup, USP (NDA 19-675/S-034), and ZANTAC 25/150 (ranitidine hydrochloride) EFFERdose Tablets and 150 (ranitidine hydrochloride effervescent) Granules (NDA 20-251/S-018).

We acknowledge receipt of your amendments submitted May 9, 2008, and January 21, 2009.

These "Changes Being Effected" supplemental new drug applications provide for the following change: Update to the Precautions and Adverse Reactions sections of the package insert (PI).

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the package insert submitted January 21, 2009. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 18-703, NDA 19-675, and NDA 20-251."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package inserts to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package inserts, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

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 an electronic copy of the letter to both these NDAs and to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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

REPORTING REQUIREMENTS

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
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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