DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-090/S-053
NDA 19-593/S-042

APPROVAL LETTER

GlaxoSmithKline
Attention: Elizabeth A. Nies
Senior Director, Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-13398

Dear Ms. Nies:

Please refer to your supplemental new drug applications dated and received April 23, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Application	Supplement	Drug Product
NDA 19-090	S-053	Zantac® (ranitidine hydrochloride) Injection and Injection Bulk Pharmacy Pack
NDA 19-593	S-042	Zantac® (ranitidine hydrochloride) Injection Premixed

We acknowledge receipt of your submission dated April 24, 2009.

These "Changes Being Effected" supplemental new drug applications provide for an addition to the **ADVERSE REACTIONS: Endocrine** subsection of the package insert.

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 agreed-upon labeling text and with the minor editorial revision listed below.

- The revision date should state September 2009 (the month in which this label is approved).

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 enclosed and submitted April 23, 2009, with the minor revision listed above. 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 19-090 and NDA 19-593."

PROMOTIONAL MATERIALS

In addition, submit three copies of the introductory promotional materials that you propose to use

for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly 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

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 a copy of the letter to this NDA and a copy 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 the requirements for an approved NDA set forth under 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}

Anne Pariser, M.D.
Acting Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19090	SUPPL-53	GLAXOSMITHKLINE	ZANTAC (RANITIDINE HCL) INJECTION
NDA-19593	SUPPL-42	GLAXOSMITHKLINE	ZANTAC PREMIX IV INJ

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/s/

ANNE R PARISER
09/04/2009