DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-090/S-045
NDA 19-593/S-033

GlaxoSmithKline
Attention: Robert Bohinski
Manager, Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Bohinski:

Please refer to your supplemental new drug application dated June 11, 2001, received June 12, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA 19-090/S-045: Zantac®(ranitidine hydrochloride) Injection
NDA 19-593/S-033: Zantac®(ranitidine hydrochloride) Injection Premixed

These "Changes Being Effected in 30 days" supplemental new drug applications provide for the addition of the words “and vasculitis” to the text under the Integumentary subsection of the ADVERSE REACTIONS section.

We also refer to your correspondences submitted on June 19 and 20, 2001.

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

We remind you of the telephone conversation on December 12, 2001, in which you committed to revising the text under the Integumentary subsection of the ADVERSE REACTIONS section at the next printing of the package insert. The revised text shall then read:

> **“Integumentary**: Rash, including rare cases of erythema multiforme. Rare cases of alopecia and vasculitis.”

Please submit final printed labeling (FPL) that is identical to the labeling text for the package insert submitted June 11, 2001, and includes the revisions indicated. These revisions are terms of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements NDA 19-090/S-045 and 19-593/S-033". Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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.

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

Sincerely,

{See appended electronic signature page}

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal
and Coagulation Drug 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/

Victor Raczkowski
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