DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-920/S-094

SmithKline Beecham Corporation d/b/a GlaxoSmithKline
Attention: Olivia Pinkett
Senior Director, GI Inflammation
2301 Renaissance Boulevard, Building 510
P.O. Box 61540
King of Prussia, PA 19406-2772

Dear Ms. Pinkett:

Please refer to your supplemental new drug application dated June 17, 2005 received June 20, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tagamet® (cimetidine hydrochloride) Tablet, 300 and 400mg.

This "Changes Being Effected" supplemental new drug application provides for the following changes:

- a revision to the container and the package insert (PI) to the extended content label (ECL) format
- deletion from PI of discontinued product information for Tagamet® Injection, Tagamet® Oral Liquid, Tagamet® Advantage Vials, and Tagamet® Pre-mixed plastic bags

We completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on June 17, 2005.

However, with the next revision of this drug label please make the following editorial changes:

(For ease of reference, the recommended additions are indicated by a single underlined and the recommended deletions are indicated by ~~strikethrough~~.)

Found in the Pharmacokinetic subsection of the Clinical Pharmacology section:

Pharmacokinetics:

~~The principal route of excretion of *Tagamet* cimetidine is the urine.~~ Following parenteral administration, most of the drug is excreted as the parent compound in the urine, the principle route of excretion of cimetidine. ~~Following parenteral administration, most of the drug is excreted as the parent compound; f~~ After oral administration, the drug is ~~more~~ extensively metabolized in which the sulfoxide is the major metabolite. Following a single oral dose, 48% of the drug is recovered from the urine after 24 hours as the parent compound.

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 Giuseppe Randazzo, Consumer Safety Officer, at (301) 796 0980.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D. Ph.D.
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/

Brian Harvey
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