DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-238/S-015

GlaxoSmithKline Consumer Healthcare
Attention: Deborah A. Panei
Regulatory Affairs Manager
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Panei:

Please refer to your supplemental new drug application dated April 3, 2006, received April 4, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tagamet HB 200 (200 mg cimetidine) tablets.

We acknowledge receipt of your submission dated September 28, 2006.

This supplemental new drug application provides for an alternate site for the bulk manufacture of Tagamet HB 200 tablets from the current GlaxoSmithKline Consumer Healthcare (GSK) site of Cidra, Puerto Rico to GSK's facilities in Mississauga, Canada. This submission also provides for Mississauga as an alternate testing site for release and stability of Tagamet HB 200 mg tablets.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (50 count carton label submitted April 3, 2006, and the Drug Facts revisions submitted September 28, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA20-238/S-015.**" Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

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