DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-238/S-013

GlaxoSmithKline
Attn: Deborah Panei
Manager, Regulatory Affairs
1500 Littleton Road
Parsippany, NJ 07054-3884

Dear Ms. Panei:

Please refer to your supplemental new drug application(s) dated April 30, 2004 received May 3, 2004 submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act for Tagamet HB (200mg cimitidine) Tablets.

We acknowledge receipt of your submissions dated November 3, 2004, November 9, 2004, March 25, 2005, and May 9, 2005.

Your submission of November 9, 2004 constituted a complete response to our November 3, 2004 Not Approvable letter.

We have completed our review of this supplemental new drug application as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on May 9, 2005.

In addition, we recommend the following revision be made at the time of next printing:

- Unbold the word "**taking**" at the end of the "Ask a doctor or pharmacist before use if you are" subheading.

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D.,M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Research and Evaluation

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Curtis Rosebraugh
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