CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-238/S-013

Name: Tagamet HB 200 Tablets
(Cimetidine Tablets 200 mg)

Sponsor: GlaxoSmithKline

Approval Date: May 10, 2005

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-238/S-013

CONTENTS

Reviews / Information Included in this Review	
Approval Letter	X
Approvable Letter	X
Labeling	X
Labeling Reviews	X
Medical Review	
Chemistry Review	
Pharmacology / Toxicology Review	
Statistical Review	
Microbiology Review	
Clinical Pharmacology / Biopharmaceutics Review	
Administrative and Correspondence Documents	X

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-238/S-013

APPROVAL LETTER

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

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/s/

Curtis Rosebraugh
5/10/05 12:50:32 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-238/S-013

APPROVABLE LETTER

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 dated April 30, 2004, received May 3, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tagamet HB 200 (200mg cimetidine) Tablets.

This supplemental new drug application proposes additional warning statements.

We have completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit revised printed labeling as follows:

1. Remove the statement "[redacted]" from the principal display panel and the top and bottom panels of carton labels and from the package insert.

2. Remove the statement "[redacted]" from the principal display panel and the package insert.

3. Delete the period from the "**Allergy alert**" warning.

4. Consolidate the "**Do not use**" warning statements to appear as a single section in carton labels and in the package insert. This section should appear under the "**Warnings**" heading as follows:

   Do not use
   - if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
   - with other acid reducers

In addition, all previous revisions, as reflected in the most recently approved package insert, must be included. To facilitate review of your submission, provide a highlighted or marked-up copy that shows the changes.

Within 10 days after the date of this letter, you are required to amend this application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with the Division of Over-the-Counter Drug Products to discuss what further steps need to be taken before the application may be approved.

This product may be considered misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with these changes before approval of this supplemental application.

If you have any questions, call LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

Charles Ganley
11/3/04 03:21:55 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-238/S-013

LABELING

KNOCKOUT FOR GLUE

Drug Facts

Read the directions and warnings before taking this product. KEEP THE PRODUCT INFORMATION SHEET. IT CONTAINS IMPORTANT INFORMATION.

Active ingredient (in each tablet)	Purpose
Cimetidine 200 mg	Acid reducer

Uses
- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages

Warnings

Allergy alert: Do not use if you are allergic to cimetidine or other acid reducers

Do not use
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have
- frequent chest pain
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with lightheadedness, sweating or dizziness
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness

Ask a doctor or pharmacist before use if you are taking
- theophylline (oral asthma medicine)
- warfarin (blood thinning medicine)
- phenytoin (seizure medicine)

If you are not sure you are taking one of these medicines, talk to your doctor or pharmacist.

Stop use and ask a doctor if
- your heartburn continues or worsens
- stomach pain continues
- you need to take this product for more than 14 days

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions
- adults and children 12 years and over:
  - to relieve symptoms, swallow 1 tablet with a glass of water
  - to prevent symptoms, swallow 1 tablet with a glass of water **right before or any time up to 30 minutes before** eating food or drinking beverages that cause heartburn
  - do not take more than 2 tablets in 24 hours
- children under 12 years: ask a doctor

Other information - store at 15-30°C (59-86°F)

Inactive ingredients cellulose, corn starch, hypromellose, magnesium stearate, polyethylene glycol, polysorbate 80, povidone, sodium lauryl sulfate, sodium starch glycolate, titanium dioxide

Questions or comments?
call toll-free 1-800-482-4394 weekdays

3 0766-5016-06 4

724

Tagamet HB 200®

Just ONE TABLET RELIEVES and PREVENTS Heartburn and Acid Indigestion

SAVE UP TO $4.00 (money-saving offer inside)

Just ONE TABLET RELIEVES and PREVENTS Heartburn and Acid Indigestion

Tagamet HB 200®

Cimetidine Tablets 200 mg/Acid Reducer

Take ANY TIME you need it:
- Before Meal
- During Meal
- After Meal

6 TABLETS (6 DOSES)

Each tablet individually sealed in a blister pack. Do not use if blister or foil is open or torn.

LOT

EXP.

Tagamet HB 200®

SAVE UP TO $4.00 (money-saving offer inside)

Tagamet HB 200®

Just ONE TABLET RELIEVES and PREVENTS Heartburn and Acid Indigestion

Distributed by:
GlaxoSmithKline Consumer Healthcare, L.P.
Moon Twp., PA 15108, Made in the U.S.A.

904eXI

724

EV CODE AREA TO BE COATING AND COPY FREE

"LOT" & "EXP" TO BE PREPRINTED CODE IS DEBOSSED

EV CODE AREA TO BE COATING AND COPY FREE

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-238/S-013

LABELING REVIEWS

Review of Labeling Supplement

Division of Over-The-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE: 4/30/04	**RECEIVED DATE:** 5/3/04
NDA/REPORT#	20-238/SLR-013
Drug Product	Tagamet HB 200 Tablets
Sponsor/Contact	Deborah A. Panei Regulatory Affairs Manager GlaxoSmithKline Consumer Healthcare 1500 Littleton Road Parsipanny, NJ 07054-3884 (973)889-2524
Active Ingredient	cimetidine
Pharmacological Category	acid reducer
Labeling submitted	30-ct, 50-ct, 70-ct, 80-ct, and 30+20-ct carton labels package insert
Review Date	8/3/04
Reviewer	Reynold Tan

Background:

The sponsor submitted draft labeling (see above) in this prior approval supplement in response to FDA's request letter dated 11/5/03, which requested labeling changes for all nonprescription acid reducers. This new class labeling consists of additional warning statements to be included in the Drug Facts labeling based upon recommendations made at the 6/21/02 Nonprescription Drugs and Gastrointestinal Drugs Joint Advisory Committee meeting.

Reviewer's comments:

1) For carton labels, the statement " [redacted] " appears in the center of the principal display panel and on the top and bottom panels, replacing the statement "Reduces Stomach Acid for Heartburn Control." This statement also appears as the first statement in the consumer package insert.

Comment: The new statement, " [redacted] " is not acceptable. The claims " [redacted] and " [redacted] are vague claims which nonspecifically relate to the speed of action. By not providing [redacted] are too general and nonspecific, with the potential for misleading or confusing the consumer. Delete this statement from the cartons and the package insert.

2) The statement " [redacted] appears in the lower right hand corner of the principal display panel and in the package insert.

Comment: Delete the statement " [redacted] that appears in the principal display panel and in the package insert. The statement is misleading and not acceptable. Other approved acid reducers are [redacted]

3) A "SAVE UP TO $4.00" promotional statement replaces a "SAVE UP TO $3.00" promotional statement on the top and side panels.

Comment: This change is acceptable.

4) The distributor address is changed from "Pittsburgh, PA 15230" to "Moon Twp., PA 19108."

Comment: This change is acceptable.

5) *Comment:* Delete the period from the "**Allergy alert**" warning.

6) The sponsor included the new class labeling warning statements on carton labels and the package insert. The warnings appear in the Drug Facts labeling format under the subheadings - "**Do not use**", "**Ask a doctor before use if you have**", and "**Stop use and ask a doctor if**" - under the "**Warnings**" heading, as requested by FDA. However, the sponsor has separated the "**Do not use**" section into two sections, a "**Do not use** if you have" section and a "**Do not use**" section. These sections appear as follows:

Do not use if you have
- trouble or pain swallowing food
- vomiting with blood
- bloody or black stools

These may be signs of a serious condition. See your doctor.

Do not use
- with other acid reducers

Comment: The sponsor should consolidate these statements under a single "**Do not use**" subheading as follows:

Do not use
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Reviewer's recommendations:

The following comments can be conveyed to the sponsor:

1) Remove the statement '[redacted] from the principal display panel and the top and bottom panels of carton labels and from the package insert.

2) Remove the misleading statement "[redacted]" from the principal display panel and the package insert. Other approved acid reducers are not[redacted]

3) Delete the period from the "**Allergy alert**" warning.

4) Consolidate the "**Do not use**" warning statements to appear as a single section in carton labels and in the package insert. This section should appear under the "**Warnings**" heading as follows:

Do not use
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Reynold Tan, Ph.D.
IDS/Biologist, HFD-560

Helen Cothran, B.S.
Team Leader, HFD-560

Table of Contents
NDA 20-238
Tagamet HB 200 Tablets
Supplement - Class Labeling Change
Prior Approval Suplement

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Note: Page numbers for each document are located in the lower left corner of each page.

7 pages of draft labeling have been removed from this portion of the document.

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/s/

Reynold Tan
8/3/04 03:06:46 PM
INTERDISCIPLINARY

Helen Cothran
8/3/04 03:45:31 PM
INTERDISCIPLINARY

Review of Labeling Supplement

Division of Over-The-Counter Drug Products (HFD-560)
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATE: 11/3/04	**RECEIVED DATE:** 11/5/04
NDA/REPORT#	NDA 20-238/SLR-013(BL)
Drug Product	Tagamet HB 200 Tablets
Sponsor/Contact	Deborah A. Panei Manager, US Regulatory Affairs GlaxoSmithKline Consumer Healthcare 1500 Littleton Road Parsipanny, NJ 07054-3884 (973)889-2524
Active Ingredient	cimetidine
Pharmacological Category	acid reducer
Labeling submitted	6-ct carton label
Review Date	12/21/04
Reviewer	Reynold Tan

Background

The sponsor had submitted a labeling supplement on 4/30/04 to incorporate OTC acid reducer class labeling for Tagamet HB 200 Tablets. After review of that 4/30/04 labeling supplement, FDA sent the sponsor an approvable (AE) letter on 11/3/04. The AE letter requested that the sponsor make the following four labeling changes:

1. Remove the statement [redacted]' from the principal display panel and the top and bottom panels of carton labels and from the package insert.

2. Remove the statement "[redacted]" from the principal display panel and the package insert.
3. Delete the period from the "**Allergy alert**" warning.
4. Consolidate the "**Do not use**" warning statements to appear as a single section in carton labels and in the package insert.

In this 11/3/04 submission, the sponsor incorporated the last three listed label changes into the printed labeling for the 6-ct carton. The sponsor stated that the proposed statement "Fast Acting and Long Lasting for Prevention and Relief of Heartburn and Acid Indigestion" does not warrant revision.

Reviewer's comments

1) The statement '[redacted]' remains on the principal display panel and the top and bottom panels of the carton label. The sponsor states that the proposed statement was a minor editorial change that was appropriately submitted through an annual report in compliance with 21 CFR 314.70(d). The sponsor states that this minor revision does not warrant removal.

Comment: The terms '[redacted] and "[redacted]" are subjective, nonspecifically relating to the speed and duration of action. Without providing reference to units of time, these terms do not provide the consumer with any useful information and are strictly promotional.

The sponsor's clinical study data show that median onset of heartburn relief is approximately 40 minutes and that cimetidine takes longer than one hour to achieve maximum reduction of gastric pH. Use of the term "[redacted]" does not communicate this information to the consumer.

The term "[redacted]" appears in the sponsor's initially proposed draft labeling. The sponsor's analyses for efficacy stipulated only that relief last longer than 30 minutes. FDA requested that the sponsor delete the term [redacted] because such a claim was unsubstantiated. The sponsor complied with FDA's request and deleted the term in the approved final printed labeling. The sponsor has since reintroduced the term in labeling submitted in the annual report.

2) The sponsor revised the statement "The Only Acid Reducer Approved to Take Before, During, or After a Meal" to read "Approved to Take Before, During, or After a Meal".

Comment: This change is acceptable.

3) The sponsor removed the period from the **"Allergy alert"** warning.

Comment: This change is acceptable.

4) The sponsor revised the **"Do not use"** section to read as follows:

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Comment: This change is acceptable.

Reviewer's recommendations

The following comments can be conveyed to the sponsor:

1) Remove the statement ' [redacted] ' from the principal display panel and the top and bottom panels of carton labels and from the package insert. The terms "[redacted]' and "[redacted]" are subjective, nonspecifically relating to the speed and duration of action. Without providing reference to units of time, these terms do not provide the consumer with any useful information and are strictly promotional. Therefore, this statement must be deleted from carton labels and the package insert.

The sponsor's clinical study data show that median onset of heartburn relief is approximately 40 minutes and that cimetidine takes longer than one hour to achieve maximum reduction of gastric pH. Use of the term '[redacted]" does not communicate this information to the consumer.

FDA has previously requested that the sponsor delete the term '[redacted]" (in proposed draft labeling submitted 8/24/94) because such a claim was unsubstantiated. The sponsor's analyses for drug efficacy stipulated only that relief last longer than 30 minutes. The sponsor complied with FDA's request and deleted the term in the approved final printed labeling. The sponsor has since reintroduced the term in labeling submitted in the annual report.

This change needs to be incorporated in labeling before this supplement can be approved.

Reynold Tan, Ph.D.
IDS/Biologist, HFD-560

Helen Cothran, B.S.
Team Leader, HFD-560

2 pages of draft labeling have been removed from this portion of the document.

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/s/

Reynold Tan
1/4/05 02:01:19 PM
INTERDISCIPLINARY

Helen Cothran
1/4/05 03:17:55 PM
INTERDISCIPLINARY

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-238/S-013

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

GlaxoSmithKline
1500 Littleton Road
Parsippany, NJ
07054-3884

Tel. 973 889 2100
Fax. 973 889 2390
www.gsk.com

April 30, 2004

NDA 20-238/S-012

Dr. Charles Ganley
Director
Division of Over-the-Counter Drug Products
Food and Drug Administration
Center for Drug Evaluation and Research
Document Control Room, HFD-560
9201 Corporate Blvd.
Rockville, MD 20850

Prior Approval Supplement: Labeling

Re: NDA 20-238: Tagamet HB 200® Tablets
(Non-prescription cimetidine tablets, 200mg tablets) -
Reply to FDA Letter dated November 5, 2003

Dear Dr. Ganley,

Reference is made to a letter from the Agency dated November 5, 2003 in regards to GlaxoSmithKline's (GSK) NDA 20-238 for Non-prescription cimetidine tablets, Tagamet HB 200®. In the letter the Agency requested a prior approval supplement with labeling changes requested for all nonprescription acid reducers.

This submission presents GSK's reply to the Agency's requested Labeling changes. Revised labeling which incorporates the requested additional warning statements is provided.

This submission is provided in electronic format. The enclosed CDROM has been confirmed to be virus-free using Norton AntiVirus Corporate Edition, version 8.00.9374, scan engine 4.1.0.15, updated 4/28/04.

If you have any questions or comments concerning this submission, please do not hesitate to contact the undersigned at (973) 889-2524 or Anthony Amitrano, Director, US Regulatory Affairs at (973) 889-2566.

Sincerely,

Deborah Panei

Deborah A.Panei
Manager, Regulatory Affairs
GlaxoSmithKline Consumer Healthcare

Enclosures: FORM FDA 356h
Labeling

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-238/S-013

PRIOR APPROVAL SUPPLEMENT

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

Dear Ms. Panei:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Tagamet HB 200 (200mg cimetidine) Tablets

NDA Number: 20-238

Supplement number: 013

Date of supplement: April 30, 2004

Date of receipt: May 3, 2004

This supplemental application provides revised labeling incorporating additional warning statements.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on July 1, 2004, in accordance with 21 CFR 314.101(a). If the application is filed, the goal date will be November 3, 2004.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Over-the-Counter Drug Products, HFD-560
Attention: Document Room
9201 Corporate Blvd
Rockville, Maryland 20850

If you have any question, call LT Keith Olin, Regulatory Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

David Hilfiker
Chief, Project Management Staff
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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/s/

David Hilfiker
6/7/04 03:09:46 PM

Food and Drug Administration
Center for Drug Evaluation and Research
Division of OTC Drug Products
Office of Drug Evaluation V

FACSIMILE TRANSMITTAL SHEET

DATE: 9/9/04

To: Deborah A. Panei Regulatory Affairs Manager	**From:** Keith J. Olin, R.Ph. Project Manger
Company: GlaxoSmithKline Consumer Healthcare	Division of Over-the-Counter Drug Products
Fax number: (973) 889-2501	**Fax number:** (301) 827-2315
Phone number: (973) 889-2524	**Phone number:** (301) 827-2249

Subject: Tagamet HB 200 labeling supplement comments NDA 20-238/S-013

Total no. of pages including cover: 2

Comments: Please, review comments and respond as soon as possible

Document to be mailed: YES X NO

Please refer to your supplemental new drug application NDA 20-238/S-013 dated 4/30/04, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tagamet HB 200 (200mg cimetidine) Tablets.

We are providing preliminary comments related to the labeling submitted. In order to ensure a timely action for this new drug application, we request that you respond to the issues listed below as soon as possible. You can fax your response to Keith Olin at (301) 827-2315.

1) Remove the statement "[redacted]" from the principal display panel and the top and bottom panels of carton labels and from the package insert.

2) Remove the statement "[redacted]" from the principal display panel and the package insert.

3) Delete the period from the "**Allergy alert**" warning.

4) Consolidate the "**Do not use**" warning statements to appear as a single section in carton labels and in the package insert. This section should appear under the "**Warnings**" heading as follows:

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

If you have any questions, contact LCDR Keith Olin, Regulatory Project Manager, at (301)827-2293.

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/s/

Keith Olin
9/29/04 02:40:46 PM

November 3, 2004

NDA 20-238/S-013

GlaxoSmithKline
1500 Littleton Road
Parsippany, NJ
07054-3884

Tel. 973 889 2100
Fax. 973 889 2390
www.gsk.com

SLR-013(BL)

Dr. Charles Ganley
Director
Division of Over-the-Counter Drug Products
Food and Drug Administration
Center for Drug Evaluation and Research
Document Control Room, HFD-HFD-560
9201 Corporate Boulevard
Rockville, MD 20850

Desk Copy to Mr. Keith Olin, Project Manager

Re: NDA 20-238: Tagamet HB 200® Tablets
(non-prescription cimetidine tablets, 200mg tablets)
Prior Approval Supplement: Labeling
Response to FDA Fax Dated September 16, 2004

Dear Dr. Ganley:

Reference is made to the FDA Fax dated September 16, 2004 concerning preliminary reviewer comments related to the prior approval labeling supplement that was submitted to the agency April 30, 2004. This supplement was submitted at the request of the FDA in their correspondence dated November 5, 2003.

The following are FDA's comments (in bold) followed by GlaxoSmithKline Consumers Healthcare's (GSK's) response (in italic) to each comment:

1) Remove the statement "[redacted]" from the principal display panel and the top and bottom of carton labels and from the package insert.

The statement "[redacted]' has been appropriately submitted through the Annual Report to the NDA as per 21 CRF 314.70(d). The proposed statement reflects only a minor

editorial change and it is GSK's opinion that this minor revision does not warrant removal.

2) Remove the statement "[redacted]" from the principal display panel.

GSK will revise this statement to read "Approved to take Before, During, or After a Meal." as per discussion with the Agency. This revised statement is an advertising claim that is truthful and not misleading, based on the Agency's approval of GSK's dosing directions.

3) Delete the period from the "Allergy alert" warning.

This change will be implemented.

4) Consolidate the "Do not use" warning statements to appear as a single section in carton labels and in the package insert. This section should appear under the "Warnings" heading as follows:

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- With other acid reducers

This change will be implemented.

A revised representative label incorporating the requested changes is provided.

GSK will follow the Agency's recommendation to implement the changes at the next printing of labeling for Tagamet HB . The next printing for Tagament HB labeling is anticipated to occur within the next 6 months.

If you have any questions, please contact the undersigned at 973-889-2524.

Deborah Panei

Deborah Panei
Manager, US Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.

November 9, 2004

NDA 20-238/S-013

GlaxoSmithKline
1500 Littleton Road
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07054-3884

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Fax. 973 889 2390
www.gsk.com

Dr. Charles Ganley
Director
Division of Over-the-Counter Drug Products
Food and Drug Administration
Center for Drug Evaluation and Research
Document Control Room, HFD-HFD-560
9201 Corporate Boulevard
Rockville, MD 20850

Desk Copy to Mr. Keith Olin, Project Manager

Re: NDA 20-238: Tagamet HB 200® Tablets
(non-prescription cimetidine tablets, 200mg tablets)
Prior Approval Supplement: Labeling
Response to FDA Fax Dated November 3, 2004

Dear Dr. Ganley:

Reference is made to the FDA Fax dated November 3, 2004 concerning preliminary reviewer comments related to the prior approval labeling supplement that was submitted to the agency April 30, 2004. This supplement was submitted at the request of the FDA in their correspondence dated November 5, 2003.

GSK acknowledges the Agency's FAX dated November 3, 2004 in Regards to the responses submitted on April 30, 2004.

Please refer to GSK's submission by FAX on November 3, 2004 and following paper submission sent by overnight mail on November 4, 2004. Please consider the submission of November 3, 2004 from GSK as a response to the Agency's FAX of the same date, November 3, 2004.

If you have any questions, please contact the undersigned at 973-889-2524.

Deborah Panei

Deborah Panei
Manager, US Regulatory Affairs
GlaxoSmithKline Consumer Healthcare, L.P.

Food and Drug Administration
Center for Drug Evaluation and Research
Division of OTC Drug Products
Office of Drug Evaluation V

FACSIMILE TRANSMITTAL SHEET

DATE: 2/8/05

To: Deborah Panei	**From:** LCDR Keith Olin, RPh. Regulatory Project Manager
Company: GlaxoSmithKline	Division of Over-the-Counter Drug Products
Fax number: 973-889-2501	**Fax number:** (301) 827-2315
Phone number: 973-889-2524	**Phone number:** (301) 827-2293

Subject: Labeling Comments NDA 20-238/S-013

Total no. of pages including cover: 2

Document to be mailed: ☐ YES ☑ NO

Please refer to your supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tagamet HB (200mg cimetidine) Tablets.

We have attached preliminary comments related to the labeling submitted November 9, 2004.

We have reviewed the referenced material and have the following comments and recommendations.

1. Delete the statement, " [redacted]", from the principal display panel and the top and bottom panels of carton labels and from the package insert.

   The terms " [redacted]" and " [redacted]" are subjective, nonspecifically relating to the speed and duration of action. Your clinical study data shows that median onset of heartburn relief is approximately 40 minutes and that cimetidine takes longer than one hour to achieve maximum reduction of gastric pH. Use of the term " [redacted]" does not communicate this information to the consumer.

   We had previously requested that you delete the term " [redacted] " (proposed draft labeling submitted August 24, 1994) because such a claim was unsubstantiated. You complied with FDA's request and deleted the term in the approved final printed labeling.

In order to ensure a timely action for this new drug application, we request that you respond to the issues listed by March 15, 2005. If you have any questions you may contact LCDR Keith Olin, Regulatory Project Manager, at (301) 827-2293.

APPEARS THIS WAY
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/s/

Keith Olin
2/28/05 03:56:19 PM