CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-205 / S-010

Trade Name: Trizivir

Generic Name: (abacavir, sulfate, lamivudine, and zidovudine)

Sponsor: GlaxoSmithKline

Approval Date: November 26, 2003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205 / S-010

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Not Approvable Letter(s)	
Final Printed Labeling	
Medical Review(s)	
Chemistry Review(s)	X
EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205 / S-010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-205/S-010

GlaxoSmithKline
Attention: Kevin A. Miller, R.Ph., RAC
Assistant Director, CMC Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Miller:

Please refer to your supplemental new drug application dated July 25, 2003, received July 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for TRIZIVIR® (abacavir sulfate, lamivudine, and zidovudine) Tablets, 300 mg of abacavir as abacavir sulfate, 150 mg of lamivudine, and 300 mg of zidovudine per tablet.

We acknowledge receipt of your submission dated November 14, 2003.

This supplemental new drug application provides for a new trade presentation, the TRIZIVIR® Tablets Convenience Pack, for use in ambulatory care clinical setting, and addition of [redacted] as an

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Virginia Yoerg, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
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/

Stephen Paul Miller
11/26/03 03:51:44 PM
NDA 21-205 / S-010 is approved
HTG

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205 / S-010

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 11/28/03	1. ORGANIZATION HFD-530	2. NDA NUMBER 21-205

3. NAME AND ADDRESS OF APPLICANT
SmithKline Beecham Corporation d/b/a Glaxo SmithKline
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101
(Correspondence: Kevin A. Miller, R.Ph., RAC, Assistant Director, CMC Regulatory Affairs, GlaxoSmithKline, PO Box 13398, Five Moore Drive, Research Triangle Park, NC 27709-3398, Phone: 919-483-5784)

4. TYPE OF SUPPLEMENT
PA

5. DOCUMENT(S)

NUMBER	DATED	RECEIVED
SCM-010	7/25/03	7/28/03
Amendment BL	11/14/03	11/17/03

6. NAME OF DRUG
Trizivir®

7. NONPROPRIETARY NAME
Abacavir sulfate+lamivudine+zidovudine

8. SUPPLEMENT PROVIDES FOR: a new trade presentation, the TRIZIVIR® Tablets Convenience Pack, for use in ambulatory care clinical setting and addition of

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
Antiviral

11. HOW DISPENSED
|X| •• || OTC

12. RELATED IND/NDA/DMF(s)
NDA 20-977
NDA 20-978
IND #45,331 (abacavir sulfate tablets and oral solution)

13. DOSAGE FORM(S)
Tablet

14. POTENCY (CIES)
300 mg of abacavir as abacavir sulfate, 150 mg of lamivudine, and 300 mg of zidovudine per tablet

15. CHEMICAL NAME
1) Abacavir sulfate: (1*S*, *cis*)-4-[2-Amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt) (2:1)
2) Lamivudine: (2*R*,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyruimidin-2-one
3) Zidovudine: 3'-Azido-3'-deoxythymidine

16. MEMORANDA

17. COMMENTS

The following supportive documentation was provided in the supplement:

Labeling Information:

- Draft Prescribing Information.
- Patient Medication Guide (no changes made).
- Sample TRIZIVIR® Tablets Convenience Pack carton.
- Sample days of the week calendar stickers.
- Sample blister strip copy.
- Color photos of the assembled TRIZIVIR® Tablets Convenience Pack carton.

CMC Information:

A few comments related to the package insert and labels were communicated to the applicant on 11/7/03 and they were satisfactorily addressed in the amendment dated 11/14/03. [redacted] was found to be acceptable by HFD-322. In conclusion, the applicant provided adequate data and made recommended changes to the package insert and labels, therefore, this supplement is recommended for approval.

18. CONCLUSIONS AND RECOMMENDATIONS

The pre-approval supplement #SCM-010 to the NDA #21-205 is recommended for approval.

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
Rao V. Kambhampati, Ph.D. Senior Regulatory Review Scientist	*[signed electronically in DFS]*	11/21/03

20. CONCURRENCE: HFD-530/TL/SMiller *[signed electronically in DFS]*

DFS CC LIST			RKambhampati			Med			PharmTox
L = Action Letter	R	L	SMiller	R	L	PM: VYoerg			Micro
R = Review				R	L				

WITHHOLD 8 PAGE(S)

B4

Chemistry Review

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

/s/

Rao Kambhampati
11/25/03 04:56:35 PM
CHEMIST

Please sign off and file into DFS.

Stephen Paul Miller
11/26/03 03:24:28 PM
CHEMIST