CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

21-205 / S-009

Trade Name: Trizivir

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

Sponsor: GlaxoSmithKline

Approval Date: October 31, 2003

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205 / S-009

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Not Approvable Letter(s)	
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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)	

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APPLICATION NUMBER:

21-205 / S-009

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-655/S040
NDA 19-951/S021
NDA 19-910/S028
NDA 20-518/S012
NDA 20-857/S013
NDA 21-205/S009

GlaxoSmithKline
Attn: Kevin A. Miller, R.Ph. RAC
Associate Director
CMC Regulatory Affairs
PO Box 13398
Five More Drive
Research Triangle Park, NC 27709

Dear Mr. Miller:

Please refer to your supplemental new drug applications dated July 9, 2003, received July 10, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

NDA 19-655/S040 Retrovir (zidovudine) Capsules, 100 mg
NDA 19-951/S021 Retrovir (zidovudine) IV Infusion, 10 mg/mL
NDA 19-910/S028 Retrovir (zidovudine) Syrup, 50 mg/5 mL
NDA 20-518/S012 Retrovir (zidovudine) Tablets, 300 mg
NDA 20-857/S013 Combivir (lamivudine/zidovudine) Tablets, 150 mg/300 mg
NDA 21-205/S009 Trizivir (abacavir sulfate, lamivudine and zidovudine) Tablets, 300 mg/150 mg/300 mg

These supplements provide for an alternate synthesis process _____ for the manufacture of zidovudine drug substance.

We completed our review of these supplemental new drug applications. These supplements are 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 Marsha Holloman, J.D., BS Pharmacy, 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
10/31/03 04:34:31 PM
NDA 19655/S-040 et al are approved

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-205 / S-009

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA **CHEMIST'S REVIEW**	**DUE DATE** 11/10/03	**1. ORGANIZATION** HFD-530	**2. NDA NUMBER** 19-655, 19-951, 19-910, 20-518 20-857, 21-205

3. NAME AND ADDRESS OF APPLICANT
Applicant name: GlaxoSmithKline
ATTN: Kevin A. Miller, R.Ph. RAC
Associate Director
CMC Regulatory Affairs
Address: PO Box 13398
Five More Drive
Research Triangle Park, NC 27709

4. TYPE OF SUPPLEMENT
PA

5. DOCUMENT(S)

NUMBERS	DATED	RECEIVED
19-655/SCS040	07/09/03	07/10/03
19-951/SCS021	07/09/03	07/10/03
19-910/SCS028	07/09/03	07/10/03
20-518/SCS012	07/09/03	07/10/03
20-857/SCS013	07/09/03	07/10/03
21-205/SCS009	07/09/03	07/10/03

6. NAME OF DRUG
Retrovir®, Combivir®, Trizivir®

7. NONPROPRIETARY NAME
Zidovudine

8. SUPPLEMENT PROVIDES FOR:
An alternate synthesis process [redacted] for the manufacture of zidovudine drug substance

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
Antiviral

11. HOW DISPENSED
|X| Rx | | OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(S)
Capsules, Injection, Syrup, Tablets

14. POTENCY (CIES)
See COMMENTS

15. CHEMICAL NAME AND STRUCTURE
3'-azido-3'-deoxy-thymidine

16. MEMORANDA

17. COMMENTS

[redacted] d

NDA 19-951/S021 Retrovir (zidovudine) IV Infusion, 10 mg/mL
NDA 19-910/S028 Retrovir (zidovudine) Syrup, 50 mg/5 mL
NDA 20-518/S012 Retrovir (zidovudine) Tablets, 300 mg
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NDA 21-205/009 Trizivir (abacavir sulfate, lamivudine and zidovudine) Tablets, 300 mg/150 mg/300 mg

Evaluation Summary:

[redacted]

18. CONCLUSIONS AND RECOMMENDATIONS
Information provided is adequate. The supplements are recommended for approval.

19. REVIEWER

NAME	1 SIGNATURE	**DATE OF DRAFT REVIEW**
Ko-Yu Lo, Ph.D.	*[signed electronically in DFS]*	10/29/03

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

DFS CC LIST		L	Ko-Yu Lo		L	Med:			PharmTox
L = Action Letter	R	L	Steve Miller	R	L	PM			Micro
R = Review						Biopharm			

WITHHOLD 8 PAGE(S)

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/s/

Ko-yu Lo
10/31/03 03:23:51 PM
CHEMIST

Stephen Paul Miller
10/31/03 04:25:51 PM
CHEMIST