CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-978 / S-009

Trade Name: Ziagen

Generic Name: (abacavir sulfate)

Sponsor: GlaxoSmithKline

Approval Date: December 24, 2002

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APPLICATION NUMBER:

20-978 / S-009

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Reviews / Information Included in this NDA Review.

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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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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-978/S-009

GlaxoSmithKline
Attn: Kevin A. Miller
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 1, 2002, received July 2, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZIAGEN® (abacavir) Oral Solution, 20 mg/mL.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate manufacturing, packaging, and testing site at nd changes to the container-closure system.

We have completed the review of this supplemental application, and it is approved.

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 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
12/24/02 02:31:26 PM
NDA 20-978 S-009 is approved
HNY

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-978 / S-009

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 1/2/03	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-978

3. NAME AND ADDRESS OF APPLICANT
GlaxoSmithKline
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709
Attn: Kevin A. Miller

4. TYPE OF SUPPLEMENT
CBE-30

5. DOCUMENT(S)

NUMBERS	DATED	RECEIVED
SCM-009	7/1/02	7/2/02

6. NAME OF DRUG
ZIAGEN® Oral Solution

7. NONPROPRIETARY NAME
abacavir oral solution

8. SUPPLEMENT PROVIDES FOR:
An alternate manufacturing, packaging, and testing site at
and changes to the container-closure system.

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
Anti-HIV

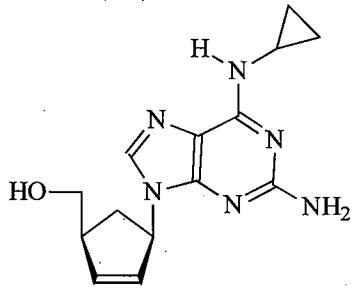
11. HOW DISPENSED
|X| Rx | | OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(S)
Oral solution

14. POTENCY (CIES)
20 mg/mL

15. CHEMICAL NAME AND STRUCTURE
(1S,cis)-4-[2-amino-6-(cyclopropylamino)-9H-purin-9-yl]-2-cyclopentene-1-methanol sulfate (salt)



16. MEMORANDA

17. COMMENTS

[redacted]

18. CONCLUSIONS AND RECOMMENDATIONS
This Supplement is therefore recommended for approval.

19. REVIEWER

NAME	SIGNATURE	DATE OF DRAFT REVIEW
George Lunn, Ph.D.	*[signed electronically in DFS]*	12/20/02

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

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

WITHHOLD 5 PAGE(S)

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/s/

George Lunn
12/23/02 01:32:45 PM
CHEMIST

Abacavir solution transfer to Mississauga

Stephen Paul Miller
12/24/02 10:52:02 AM
CHEMIST