CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-857 / S-011

Trade Name: Epivir

Generic Name: Lamivudine

Sponsor: GlaxoSmithKline

Approval Date: September 13, 2002

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APPLICATION NUMBER:

20-857 / S-011

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
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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:

20-857 / S-011

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-564/S-017
NDA 20-596/S-018
NDA 20-857/S-011
NDA 21-003/S-003
NDA 21-004/S-003

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 applications dated March 20, 2002, received March 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for:

EPIVIR® (lamivudine) Tablets, 150 mg and 300 mg,
EPIVIR® (lamivudine) Oral Solution, 10 mg/mL,
COMBIVIR® (lamivudine and zidovudine) Tablets, 150 mg of lamivudine, and 300 mg of zidovudine per tablet,
EPIVIR-HBV® (lamivudine) Tablets, 100 mg, and
EPIVIR-HBV® (lamivudine) Oral Solution, 5 mg/mL.

These "Changes Being Effected in 30 days" supplemental new drug applications provide for approval of Glaxo Wellcome Manufacturing, [redacted] as an alternate manufacturing site for [redacted] of lamivudine drug substance. This site will also be used for quality control testing for the [redacted] and for quality control and stability testing for lamivudine drug substance. These submissions also include alternate analytical methods for [redacted]

We have completed the review of these supplemental applications, and they are 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.

Food and Drug Administration
Rockville MD 20857

If you have any questions, call Christine Lincoln, RN, MS, MBA, 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
9/13/02 04:04:07 PM
NDAs 20-564/S-017, 20-596/S-018, 20-857/S-011, 21-003/S-003 and 21-004/S-00

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-857 / S-011

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW	DUE DATE 9/21/02	1. ORGANIZATION HFD-530	2. NDA NUMBER 20-857

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-011	3/20/02	3/21/02

6. NAME OF DRUG
COMBIVIR® Tablets

7. NONPROPRIETARY NAME
lamivudine/zidovudine tablets

8. SUPPLEMENT PROVIDES FOR:
An alternate manufacturing, quality control testing, and stability testing site at [redacted] for intermediate [redacted] and lamivudine drug substance

9. AMENDMENTS/DATES

10. PHARMACOLOGICAL CATEGORY
Anti-HIV

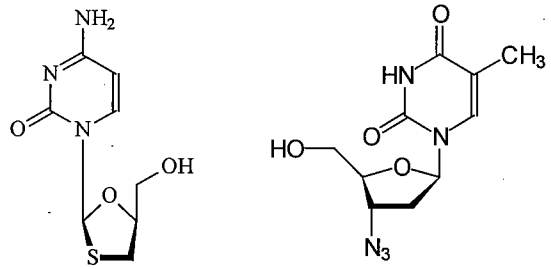
11. HOW DISPENSED
|X| Rx | | OTC

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM(S)
Tablets

14. POTENCY (CIES)
150 mg/300 mg

15. CHEMICAL NAME AND STRUCTURE
(2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one / 3'-azido-3'-deoxythymidine



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]*	28-Aug-2002

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

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

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/s/

George Lunn
8/28/02 02:40:46 PM
CHEMIST

Lamivudine

Stephen Paul Miller
9/10/02 05:09:21 PM
CHEMIST