

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-596 / S-010

Trade Name: Epivir

Generic Name: (Lamivudine)

Sponsor: GlaxoSmithKline

Approval Date: October 18, 1999

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APPLICATION NUMBER:

20-596 / S-010

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APPROVAL LETTER



NDA 20-596/S010

Food and Drug Administration
Rockville MD 20857

OCT 18 1999

Glaxo Wellcome Inc.
Attention: James A. Zisek
Assistant Director/CMC Submission
Five Moore Drive,
P. O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Zisek:

Please refer to your supplemental new drug application dated June 17, 1999, received June 18, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EPIVIR® (lamivudine) Oral Solution, 10 mg/mL.

This supplemental new drug application provides for reformulation of EPIVIR® oral solution as an ethanol-free solution.

We acknowledge receipt of your amendments dated August 3, 1999 and October 12, 1999.

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, contact Christine Kelly, RN, MS, MBA, Regulatory Health Project Manager, at (301) 827-2335.

Sincerely yours,

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

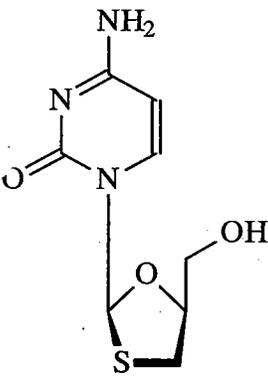
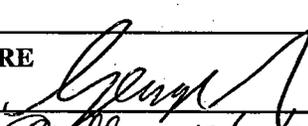
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CHEMISTRY REVIEW(S)

OCT 18 1999

SUPPLEMENTAL NDA CHEMIST'S REVIEW		1. ORGANIZATION HFD-530	2. NDA NUMBER 20-596			
3. NAME AND ADDRESS OF APPLICANT (City and State) Glaxo Wellcome Inc. Five Moore Drive, P.O. Box 13398 Research Triangle Park, NC 27709			4. AF NUMBER			
			5. SUPPLEMENT(S)			
			NUMBER(S) SCF-010	DATE(S) 6/17/99		
6. NAME OF DRUG EPIVIR® Oral Solution		7. NONPROPRIETARY NAME Lamivudine oral solution				
8. SUPPLEMENT(S) PROVIDES FOR: Reformulation of Epivir oral solution as an ethanol-free solution.			9. AMENDMENTS / REPORTS Amendments of 8/3/99 and 10/12/99			
10. PHARMACOLOGICAL CATEGORY Anti-HIV		11. HOW DISPENSED <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S)		
13. DOSAGE FORM(S) Oral solution		14. POTENCY(IES) 10mg/mL				
15. CHEMICAL NAME AND STRUCTURE (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one			16. MEMORANDA			
						
17. COMMENTS See Page 2.						
18. CONCLUSIONS AND RECOMMENDATIONS This Supplement describes the reformulation of Epivir (lamivudine) oral solution for the treatment of HIV as an ethanol-free solution. [redacted] have been removed, the concentrations of [redacted] have been increased, [redacted] has been added, and the pH has been increased from [redacted]. The proposed formulation, apart from the concentration of lamivudine, is identical to the approved HBV oral solution for the treatment of hepatitis B. The specifications are adequate, the analytical methods are fully described, and satisfactory batch analysis data are presented for 3 batches. The proposed expiration dating period is 24 months and 24 months of satisfactory stability data are presented. This Supplement is therefore recommended for approval.						
19. REVIEWER						
NAME George Lunn, Ph.D.		SIGNATURE 		DATE COMPLETED 10/18/99		
20. CONCURRENCE: HFD-530/SMiller  10/18/99						
DISTRIBUTION	<input checked="" type="checkbox"/>	Original Jacket	<input checked="" type="checkbox"/>	GLunn	<input checked="" type="checkbox"/>	CKelly
	<input checked="" type="checkbox"/>	Division File	<input checked="" type="checkbox"/>	SMiller	<input checked="" type="checkbox"/>	Biopharm
	<input checked="" type="checkbox"/>	HFD-830/CChen	<input checked="" type="checkbox"/>	BStyrt	<input checked="" type="checkbox"/>	Micro

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