CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-564 / S-017

Trade Name: Epivir

Generic Name: (Lamivudine)

Sponsor: GlaxoSmithKline

Approval Date: September 13, 2002
## Reviews / Information Included in this NDA Review.

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APPROVAL LETTER
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, an alternate manufacturing site for... This site will also be used for quality control testing for the... and for stability testing for lamivudine drug substance.

These submissions also include alternate analytical methods for... for...

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.
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
APPLICATION NUMBER:

20-564 / S-017

CHEMISTRY REVIEW(S)
**SUPPLEMENTAL NDA CHEMIST’S REVIEW**

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<th>DUE DATE</th>
<th>1. ORGANIZATION</th>
<th>2. NDA NUMBER</th>
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<tr>
<td>9/21/02</td>
<td>HFD-530</td>
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3. **NAME AND ADDRESS OF APPLICANT**
   Glaxo Wellcome Inc.
   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
   SCM-017                DATED 3/20/02
   RECEIVED 3/21/02

6. **NAME OF DRUG**
   EPIVIR® Tablets

7. **NONPROPRIETARY NAME**
   lamivudine tablets

8. **SUPPLEMENT PROVIDES FOR:**
   An alternate manufacturing, quality control testing, and stability testing site a

9. **AMENDMENTS/DATES**

10. **PHARMACOLOGICAL CATEGORY**
    Anti-HIV

11. **HOW DISPENSED**
    [X] B [ ] OTC

12. **RELATED IND/NDA/DMF(s)**

13. **DOSSAGE FORM(S)**
    Tablets

14. **POTENCY (CIES)**
    150 mg

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

![Chemical Structure](image)

16. **MEMORANDA**

17. **COMMENTS**

   on 4/12/02. On 8/21/02 an overall recommendation of “Acceptable” was made.

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

19. **REVIEWER**
    NAME: George Lunn, Ph.D.
    SIGNATURE: [signed electronically in DFS]
    DATE OF DRAFT REVIEW: 27-Aug-2002

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

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