CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-564/S-012
20-596/S-013

ADMINISTRATIVE DOCUMENTS

Division of Antiviral Drug Products

PROJECT MANAGER REVIEW

Application Number: 20-564/S-011 and 012
20-596/S-012 and 013

Name of Drug: Epivir™ (lamivudine) Tablets and Oral Solution

Sponsor: Glaxo Wellcome Inc.

Material Reviewed

Submission Date: March 30, 2001

Receipt Date: April 2, 2001

Background and Summary Description:
This submission contains final printed labeling for approved supplements N20-564/011,012, and 20-596/012,013.

The final printed labeling was submitted in response to the supplements 011 and 012 approval letter dated January 5, 2001, and supplement 012, and 013 approval letter dated March 6, 2001. Supplements 011, and 012 were approved on draft labeling submitted by the sponsor November 8, 2000, and supplement 012 and 013 was approved on draft labeling submitted by the sponsor January 23, 2001.

The March 30, 2001 package insert and patient package insert were compared electronically to the labeling submitted January 23, 2001, and approved March 6, 2001 for supplement 012 and 013. Supplements 12 and 013 also contained the approved changes from supplements 011 and 012.

Review

The labels were compared electronically and there were no changes noted.

Conclusions

An acknowledge and retain letter will be issued to the sponsor.

Christine Lincoln, RN, MS, MBA
Regulatory Health Project Manager
Division of Antiviral Drug Products

FINAL PRINTED LABELING REVIEW

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/s/

Christine Lincoln
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CSO

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-564/S-011 and S-012
NDA 20-569/S-012 and S-013

GlaxoSmithKline
Attention: Mary E. Martinson
Product Director, Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Martinson:

We acknowledge receipt of your March 30, 2001 submission containing final printed labeling in response to our January 5, 2001 and March 6, 2001 letters approving your supplemental new drug application for Epivir® (lamivudine), 150mg tablets and oral solution.

We have reviewed the labeling that you submitted in accordance with our January 5, 2001 and March 6, 2001 letters and we find it acceptable.

If you have any questions, call Christine Lincoln, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

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/s/

Debra Birnkrant
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NDA 20596 SLR 013, NDA 20596 SLR 012, NDA 20564 SLR 012, NDA 20564 SLR 011