

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

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

MEDICAL REVIEW

NDA: 20564 (SLR-012); 20596 (SLR-013)

**Medical Officer's Review
Supplemental NDA**

Date submitted: August 26, 1999
Date received: August 27, 1999
Date assigned: September 9, 1999
Draft MOR completed: November 5, 1999
Revisions to MOR completed: September 2, 2000

Applicant: Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709

Drug name: Lamivudine (Epivir®, 3TC, GR109714X)

Dosage form: Tablets 150 mg and solution 10 mg/ml

Route of administration: Oral

Proposed indication: Treatment of HIV infection

Related INDs and NDAs:

NDA 20-564 (lamivudine tablets 150 mg)
NDA 20-596 (lamivudine solution 10 mg/ml)
NDA 20-857 (lamivudine/zidovudine tablets)
NDA 21-003 (lamivudine for hepatitis B)
NDA 21-004 (lamivudine solution for hepatitis B)

Amendment: March 21, 2000

This one-volume submission contains revised draft labeling for Epivir, lamivudine for treatment of HIV infection. The revised labeling is submitted as a supplement providing for geriatric labeling. The applicant has concluded that clinical studies have not included a large enough number of geriatric patients to evaluate similarities or differences compared to younger patients, and has proposed labeling to reflect this. Changes in wording were suggested in a comment to the applicant, for closer correspondence to language models in 21 CFR 201.57(f)(10). The proposed label wording was also referred to Biopharmaceutics because information from a pharmacokinetic study in a small number of elderly Japanese subjects was included (and not considered adequate for label information). The proposed revised wording was discussed with the Biopharmaceutics reviewer who considered it acceptable and had no further comments. The revised language regarding geriatric patients is in accordance with DAVDP discussions of geriatric label wording and can be approved as revised, as soon as agreement is reached on another pending supplement that the applicant elected to cross-reference. The applicant has been asked to address similar considerations for geriatric label language regarding the analogous portions of the Combivir and Epivir-HBV package inserts.

Barbara Styrt, M.D., M.P.H.
Medical Officer, HFD-530

Concurrence:

HFD-530/Dir/HJolson
HFD-530/MTL/SKukich

cc:

HFD-530/NDA20564
HFD-530/NDA20596
HFD-530/Division File
HFD-530/Pharm/Verma
HFD-530/Micro/Battula
HFD-530/Chem/Lunn
HFD-530/Stat/Soon
HFD-530/Biopharm/Reynolds
HFD-340
HFD-530/MO/BStyrt
HFD-530/MTL/SKukich
HFD-530/CSO/Lincoln

c:\data\NDA20564\morSL012