

NDA: 20-857 (SLR-008)

AUG 29 2000

**Medical Officer's Review
NDA Labeling Supplement**

Date submitted: August 26, 1999
Date received: August 27, 1999
Date assigned: September 13, 1999
Draft MOR completed: February 15, 2000
Revisions to MOR completed: August 15, 2000

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

Drug name: Combivir™ (lamivudine/zidovudine tablets)

Dosage form: Tablets containing lamivudine 150 mg and zidovudine 300 mg

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)

Amendments: August 31, 1999
April 3, 2000
August 10, 2000

In an amendment dated August 10, 2000, the applicant restored the box warning wording, and flagged changes from _____

_____ number of these changes involve portions of the labeling customarily reviewed by Pharmacology/Toxicology, and were therefore informally discussed with Pharmacology/Toxicology. As informal comments from Chemistry, Biopharmaceutics, and Pharmacology/Toxicology have indicated no objections, the geriatric wording now appears consistent with the CFR and with Division consensus on geriatric wording, and the box warning is consistent with the previously approved version, the labeling in this amendment appears suitable for approval.

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

Concurrence:

HFD-530/Dir/HJolson *HJ 8/29/00*
HFD-530/MTL/SKukich *10/00*

cc:

HFD-530/NDA20857
HFD-530/Division File
HFD-530/Pharm/Farrelly
HFD-530/Micro/Battula
HFD-530/Chem/Lo
HFD-530/Stat/Aras
HFD-530/Biopharm/Reynolds
HFD-340
HFD-530/MO/BStyr
HFD-530/MTL/SKukich
HFD-530/CSO/Kelly

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