

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 20-857/S-008**

**APPROVAL LETTER**

SEP 29 2000

NDA 20-857/S-008

GlaxoWellcome Inc.  
Attention: Martha Anne A. Moore, R.Ph.  
Antiviral Group-Regulatory Affairs  
Five Moore Drive  
P.O. Box 13398  
Research Triangle Park, NC  
27709

Dear Ms. Moore:

Please refer to your supplemental new drug application dated August 26, 1999, received August 27, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combivir™ (lamivudine/zidovudine), 150mg/300mg tablets.

We acknowledge receipt of your submissions dated August 31, 1999, and April 3, and August 10, 2000.

This supplemental new drug application provides for a geriatric use section in the Combivir label.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 10, 2000).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. Please also submit an MS Word copy of the label on a disk as a desk copy. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-857/S-008." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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

Sincerely,



Heidi M. Jolson, M.D., M.P.H.  
Director  
Division of Antiviral Drug Products  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Concurrence:

HFD-530/PT/Verma 1/19/2000  
HFD-530/BPH/DiGiacinto 9/2/00  
HFD-530/Chem/Lo 1/19/00  
HFD-530/MO/Styr 2/1/00  
HFD-530/MO TL/Kukich 2/1/00  
HFD-530/SCSO/DeCicco 2/00  
HFD-530/DD/Birkrant 9/25/00

cc:

Archival NDA 20-857  
HFD-530/Div. Files 20-857  
HFD-530/C.Lincoln  
HFD-530/Styrt  
HFD-530/Kukich  
HF-2/MedWatch (with labeling)  
HFD-002/ORM (with labeling)  
HFD-104/ADRA (with labeling)  
HFD-40/DDMAC (with labeling)  
HFI-20/Press Office (with labeling)  
HFD-400/OPDRA (with labeling)  
HFD-613/OGD (with labeling)  
HFD-21/ACS (with labeling) - for drug discussed at advisory committee meeting.  
HFD-095/DDMS-IMT (with labeling)  
HFD-830/DNDC Division Director  
DISTRICT OFFICE

Drafted by: cmk/September 13, 2000

Filename: v:/davdp/kelly/nda/20857/letters/ap008

**APPROVAL (AP)**