



NDA 20-857/S-012

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

Dear Ms. Moore:

Please refer to your supplemental new drug application dated June 14, 2002 received June 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Combivir™ (lamivudine/zidovudine) 150mg and 300mg tablets.

We also acknowledge receipt of your submissions dated August 20, and September 10, 2002.

Supplemental application 012 provides for the addition of fat redistribution information.

We have completed the review of this supplemental application, as amended, 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, this 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 September 10, 2002).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). In addition, please submit a Microsoft Word version of the label electronically. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-857/S-009, 010, and 012." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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

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}

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Debra Birnkrant
10/8/02 12:51:59 PM
NDA 20-857