



NDA 20-857/S-020

GlaxoSmithKline  
Attention: Susan L. Watts, Ph.D.  
Associate Director  
P.O. Box 13398  
Five Moore Drive  
Research Triangle Park, NC 27709

Dear Dr. Watts:

Please refer to your supplemental new drug application dated October 9, 2006, received October 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for COMBIVIR® (lamivudine/ zidovudine) tablets.

This “Changes Being Effected” supplemental new drug application provides for:

- ***Changes to the MICROBIOLOGY section of the US package insert.***

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
5515 Security Lane  
HFD-001, Suite 5100  
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Paras M. Patel, Regulatory Project Manager, at (301) 796-0783.

Sincerely,

*{See appended electronic signature page}*

Debra Birnkrant, M.D.

Director

Division of Antiviral Products

Office of Antimicrobial Products

Center for Drug Evaluation and Research

Enclosure (Approved Labeling)

-----  
**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  
10/25/2006 09:30:46 AM  
NDA 20-857