



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-564/S-028

GlaxoSmithKline
ATTN: Martha Anne Auld Moore, R.Ph.
Senior Director, Antiviral/Antibacterial US Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Ms. Moore :

Please refer to your supplemental new drug application dated August 3, 2007, received August 3, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EPIVIR® (lamivudine) Scored Tablets, 150 mg.

We acknowledge receipt of your submissions dated September 3, 2007, October 24, 2007, November 19, 2007, December 5, 2007, December 18, 2007, January 18, 2008 and January 30, 2008.

This supplemental new drug application provides for the use of EPIVIR® (lamivudine) scored tablets, 150 mg for dosing in pediatric patients for whom a solid oral dosage form is appropriate.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 31, 2008.

This supplemental new drug application does not invoke the PEDIATRIC RESEARCH EQUITY ACT (PREA).

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).

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If you have any questions, call Paras M. Patel, R.PH, 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: (Final Draft Label):

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

/s/

Jeffrey Murray
2/1/2008 03:50:51 PM