DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-655/S-048
NDA 20-518/S-018

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Martha Anne A. Moore, R.Ph.
Senior Director, Infectious Diseases, US Regulatory Affairs
P.O. Box 13398
Five Moore Drive,
Research Triangle Park, NC 27709

Dear Ms. Moore:

Please refer to your supplemental new drug applications dated and received May 7, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RETROVIR® (zidovudine) capsules and tablets.

We acknowledge receipt of your submissions dated June 5, 2009, June 19, 2009, and October 26, 2009.

These "prior approval" supplemental new drug applications update the package inserts with pediatric dosing information for the RETROVIR syrup and the "Patient Counseling" section with information related to HIV-1/HCV co-infection, lactic acidosis/hepatomegaly and myopathy.

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

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm that is identical to the enclosed labeling (text for the package insert and patient package insert).For administrative purposes, please designate these submissions, "SPL for approved NDA 19-655/S-048 and NDA 20-518/S-018.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Robert G. Kosko, Jr., Pharm.D., M.P.H., Regulatory Project Manager, at (301) 796-3979.

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
Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19655	SUPPL-48	GLAXOSMITHKLINE	RETROVIR (ZIDOVUDINE) CAPSULES
NDA-20518	SUPPL-18	GLAXOSMITHKLINE	RETROVIR (ZIDOVUDINE) TABS 200MG/300MG

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

/s/

JEFFREY S MURRAY
11/06/2009