DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020977/S-022
NDA 020978/S-026
NDA 021205/S-028
NDA 021652/S-013

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

ViiV Healthcare Company c/o GlaxoSmithKline
Attention: Susan L. Watts, Ph.D.
Director-US Infectious Diseases
Global Regulatory Affairs
Room 5.5381.5C
5 Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Dear Dr. Watts:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 6, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ziagen (abacavir sulfate) Tablets (NDA 20-977), Ziagen (abacavir sulfate) Oral Solution (NDA 20-978), Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets (NDA 21-205), and Epzicom (abacavir sulfate and lamivudine) Tablets (NDA 21-652).

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated May 12, 2011.

These supplemental new drug applications provide for elimination of the approved risk evaluation and mitigation strategy (REMS).

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Ziagen (abacavir sulfate) Tablets and Oral Solution was originally approved July 18, 2008, and the REMS for Trizivir (abacavir sulfate, lamivudine, and zidovudine) and Epzicom (abacavir sulfate and lamivudine) were originally approved on March 9, 2009. The most recent REMS modification for Ziagen (abacavir sulfate) Tablets and Oral Solution was approved on August 4, 2010. The most recent REMS modification for Trizivir (abacavir sulfate, lamivudine, and zidovudine) was approved on March 31, 2011. The most recent REMS modification for Epzicom (abacavir sulfate and lamivudine) was approved on February 2, 2011.

These REMS consist of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Ziagen (abacavir sulfate) Tablets, Ziagen (abacavir sulfate) Oral Solution, Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets, and Epzicom (abacavir sulfate and lamivudine) Tablets.

We have determined that it is no longer necessary to include the Medication Guide as an element of the approved REMS and that a REMS is no longer necessary to ensure that the benefits of Ziagen (abacavir sulfate) Tablets, Ziagen (abacavir sulfate) Oral Solution, Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets, and Epzicom (abacavir sulfate and lamivudine) Tablets outweigh their risks. Therefore, we agree with your proposal and the REMS for Ziagen (abacavir sulfate) Tablets, Ziagen (abacavir sulfate) Oral Solution, Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets, and Epzicom (abacavir sulfate and lamivudine) Tablets are no longer required. We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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 or the Division's main number at (301) 796-1500.

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

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

/s/

KENDALL A MARCUS
05/13/2011