DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-977/S-020
NDA 20-978/S-024
NDA 21-205/S-024
NDA 21-652/S-011

REMS MODIFICATION APPROVAL

ViiV Healthcare Company
Attention: Susan L. Watts, Ph.D.
Director, ID, GRA, GlaxoSmithKline
PO Box 13398
5 Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Watts:

Please refer to your supplemental new drug applications dated January 25, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ziagen (abacavir sulfate) Tablets (NDA 20-977/S-020), Ziagen (abacavir sulfate) Oral Solution (NDA 20-978/S-024), Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets (NDA 21-205/S-024), and Epzicom (abacavir sulfate and lamivudine) Tablets (NDA 21-652/S-011).

We also acknowledge receipt of your amendments dated June 11, 2010 and July 16, 2010; and your risk evaluation and mitigation strategy (REMS) assessment dated January 25, 2010.

These "Prior Approval" supplemental new drug applications provide for proposed modifications to the approved REMS for these products.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Ziagen (abacavir sulfate) Tablets and Oral Solution was approved July 18, 2008, and the REMS for Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets and Epzicom (abacavir sulfate and lamivudine) Tablets were approved on March 9, 2009. The three REMS for all of these abacavir-containing products consist of a Medication Guide and a timetable for submission of assessments of the REMS. We also refer to our letter dated May 14, 2010, that notified you to submit a proposed REMS modification based on the REMS assessment for these products dated January 25, 2010. Your proposed modifications to the REMS consist of modifications to the timetable for submission of assessments of the REMS.

Your three proposed modified REMS for these abacavir-containing products, submitted on June 11, 2010, and appended to this letter, are approved.

For Trizivir (abacavir sulfate, lamivudine, and zidovudine) Tablets and Epzicom (abacavir sulfate and lamivudine) Tablets, there are no changes to the REMS assessment plans described in our March 9, 2009 letters. For Ziagen (abacavir sulfate) Tablets and Oral Solution, there are no changes to the REMS assessment plan described in our November 7, 2008 letter.

We remind you that the requirements for assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 20-977, NDA 20-978, NDA 21-205, and
NDA 21-652
REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 20-977, NDA 20-978, NDA 21-205, and
NDA 21-652 -PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENTS (NEW INDICATION FOR USE)
FOR NDA 20-977, NDA 20-978, NDA 21-205, and
NDA 21-652
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)>>

If you do not submit electronically, please send 5 copies of REMS-related submissions.

If you have any questions, call Carrie Ceresa, Pharm D., MPH, Acting Safety Project Manager, at (301) 796-4108.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE:
REMS and Medication Guides

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21652	SUPPL-11	VIIV HEALTHCARE CO	EPIVIR/ZIAGEN(ABACAVIR SULFATE/LAMIVUDIN
NDA-21205	SUPPL-24	VIIV HEALTHCARE CO	TRIZIVIR
NDA-20978	SUPPL-24	VIIV HEALTHCARE CO	ZIAGEN
NDA-20977	SUPPL-20	VIIV HEALTHCARE CO	ZIAGEN

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
08/04/2010