DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21652/S-18

SUPPLEMENT APPROVAL

ViiV Healthcare Company
Attention: Natasha Smith
Regulatory Project Manager
Five Moore Drive, PO Box 13398 Mailstop 5.5B
Research Triangle Park, NC 27709

Dear Ms. Smith:

Please refer to your Supplemental New Drug Application (sNDA) dated August 19, 2014, received August 19, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for EPZICOM® (abacavir sulfate and lamivudine), 600 mg/300 mg tablets.

We acknowledge receipt of your amendments dated February 9, 2015, February 13, 2015 and February 17, 2015.

This supplemental new drug application proposes the following changes:

- To update the Use in Specific Populations-Pregnancy section with aggregate data from the Antiretroviral Pregnancy Registry and published literature and to revise the section based upon the final rule, "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling."

- To add a Lactation subsection to Use in Specific Populations section of the package insert.

- To update the OVERDOSAGE section with patient monitoring information and to provide the effects of various methods of dialysis on the removal of lamivudine from the system.

- To update CLINICAL PHARMACOLOGY, Pharmacokinetics subsection 12.3; subtitled "Pregnancy: See Use in Specific Populations (8.1)"; to remove information regarding presence of abacavir and lamivudine in breast milk.

- To update the Patient Counseling section with additional counseling information about HIV-1 Infection and Epzicom.

- To update the "What Should I tell my healthcare provider before taking Epzicom?" section of the Medication Guide with information regarding the use of Epzicom during pregnancy.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Mammah Sia Borbor, M.S., M.B.A., Regulatory Project Manager, at (301) 796-7731 or (301) 796-1500.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Content of Labeling

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

/s/

POONAM MISHRA
02/19/2015