DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20564/S-34
NDA 20596/S-33

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 EPIVIR® (lamivudine), 300 mg and 150 mg tablets and EPIVIR® (lamivudine), 10 mg per mL oral solution.

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

These Prior Approval supplemental new drug applications propose 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 update Warnings and Precautions, Use with Other Lamivudine and Emtricitabine-containing Products section to include elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate.

We have completed our review of these supplemental applications, as amended. They are 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), 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 these NDAs, 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 these supplemental applications, 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