DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21205/S-34

**SUPPLEMENT APPROVAL**

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

Dear Ms. Smith:

Please refer to your Supplemental New Drug Application (sNDA) dated March 31, 2015, received March 31, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TRIZIVIR (abacavir, lamivudine, and zidovudine) tablets, 300 mg/ 150 mg/300 mg.

We acknowledge receipt of your amendments dated April 28, 2015, May 13, 2015, July 6, 2015, August 7, 2015, August 31, 2015, September 10, 2015, September 16, 2015, September 21, 2015, and September 28, 2015.

This "Prior Approval" supplemental new drug application proposes to update the labeling with the following information:

- To update and streamline the language related to abacavir hypersensitivity reaction so that the sections are concise.
- To revise the generic name, abacavir sulfate, to abacavir.
- To update the DOSAGE AND ADMINISTRATION and CONTRAINDICATIONS sections with new information regarding the HLA-B*5701 allele.
- To update the Boxed Warning, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS, Clinical Trials Experience sections with updated hypersensitivity reaction information.
- To revise the information in WARNINGS AND PRECAUTIONS, subsections 5.1, 5.4, 5.5, 5.6, and 5.11.
- To delete drug-drug interaction information for lamivudine plus interferon and ribavirin based regimens in the DRUG INTERACTIONS section.

- To update the USE IN SPECIFIC POPULATIONS and CLINICAL PHARMACOLOGY, Pharmacokinetics subsection, with impaired renal function and impaired hepatic function information.

- To revise the OVERDOSAGE section.

- To modify the drug-drug interaction information for abacavir, lamivudine, and zidovudine in the CLINICAL PHARMACOLOGY section.

- To add interferon alpha and lamivudine drug-drug interaction information in the CLINICAL PHARMACOLOGY section.

- To update the CLINICAL PHARMACOLOGY, Microbiology and Antiviral Activity subsections, with additional information.

- To update the PATIENT COUSELING INFORMATION section to add information on Immune Reconstitution Syndrome and update the Information about HIV-1 subsection.

- To update the MEDICATION GUIDE with language that is consistent with the Agency's current standards.

## APPROVAL & LABELING

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, 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).

**PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf. Information and Instructions for completing the form can be found at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

**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 Christian Yoder, Regulatory Project Manager, at (240) 402-9990 or (301) 796-1500.

Sincerely,

*{See appended electronic signature page}*

Poonam Mishra, MD, MPH
Deputy Director for Safety
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

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/s/

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POONAM MISHRA
09/30/2015