DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20977/S-26
NDA 20978/S-30

**SUPPLEMENT APPROVAL**

ViiV Healthcare Company
c/o Glaxo-Smith Kline
Attention: Martha Anne Auld, R.Ph.,
Senior Director, Global Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Auld:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 23, 2013, received May 23, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ziagen® (abacavir sulfate) tablet, 300 mg and Ziagen® (abacavir sulfate), oral solution, 20 mg/ml.

We acknowledge receipt of your amendments dated August 9, 2013.

These "Prior Approval" supplemental new drug applications propose the following revisions to the CLINICAL PHARMACOLOGY, Microbiology section of the labeling:

- To remove information that might imply synergy in vivo
- To add antiviral activity information from an abacavir sulfate and lamivudine in vitro combination study

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, text for the patient 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 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 Karen Winestock, Chief, Project Management Staff, at (301) 796-0834.

Sincerely,

*{See appended electronic signature page}*

Kendall Marcus, MD
Deputy Director of Safety
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
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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KENDALL A MARCUS
09/11/2013