DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205551/S-13

SUPPLEMENT APPROVAL

ViiV Healthcare Company
c/o GlaxoSmithKline
Attention: Stephen Hyatt, RAC
Project Manager, Global Regulatory Affairs
Five Moore Drive, PO box 13398
Research Triangle Park, NC 27709

Dear Mr. Hyatt:

Please refer to your Supplemental New Drug Application (sNDA) dated November10, 2017, received November 13, 2017, and your amendments, submitted under section 505(b)/ of the Federal Food, Drug, and Cosmetic Act (FDCA) for TRIUMEQ (abacavir sulfate, dolutegravir, and lamivudine) 600 mg/50 mg/300 mg, tablet.

This Prior Approval supplemental new drug application proposes the following changes:

1. Remove lactic acidosis and severe hepatomegaly with steatosis information from the BOXED WARNING
2. Remove fat redistribution information from the WARNINGS AND PRECAUTIONS and other sections of the labeling
3. Update WARNINGS AND PRECAUTIONS section to include revised information related to the risk of myocardial infarction
4. Inclusion of lamivudine-sorbitol drug interaction information to the DRUG INTERACTIONS and CLINICAL PHARMACOLOGY sections
5. Update the CLINICAL PHARMACOLOGY, Pharmacokinetics section with abacavir and lamivudine transporter data.

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 and text for the 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 include 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 Linda C. Onaga, MPH Regulatory Project Manager, at (301) 796-0759 or the Division mainline at (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
05/11/2018
on behalf of Debra Birnkrant, MD