DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20857/S-033

SUPPLEMENT APPROVAL

ViiV Healthcare Company
Attention: Stephen Hyatt, RAC
Project Manager, Global Regulatory Affairs
Five Moore Drive
PO Box 13398
Research Triangle, NC 27709

Dear Mr. Hyatt:

Please refer to your Supplemental New Drug Application (sNDA) dated November 10, 2017 and received on November 13, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for COMBIVIR® (lamivudine and zidovudine tablets).

This Prior Approval supplemental new drug application provides for the following revisions to the Prescribing Information:

- BOXED WARNING, Lactic acidosis and Severe Hepatomegaly with Steatosis: Revised to include the components of Combivir.
- WARNINGS AND PRECAUTIONS, subsection 5.3 Lactic Acidosis and Severe Hepatomegaly with Steatosis: Updated information to include female sex and obesity as risk factors.
- WARNINGS AND PRECAUTIONS, subsection 5.8 Lipoatrophy: Removal of general information on fat redistribution and updated information specific to lipoatrophy.
- DRUG INTERACTIONS and CLINICAL PHARMACOLOGY, Pharmacokinetics sections were updated to include drug interaction information with sorbitol-containing medicines.
- Corresponding changes were made to the PATIENT COUNSELING INFORMATION.

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 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 CAPT Anitra Johnson, DHSc, MSN, RN, Regulatory Project Manager, at (301) 796-4876.

Sincerely,

{See appended electronic signature page}
Debra Birnkrant, M.D.
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
04/27/2018
on behalf of Debra Birnkrant, MD