DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19655/S-058
NDA 19910/S-045
NDA 19951/S-036

SUPPLEMENT APPROVAL

ViiV Healthcare Company
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 Applications (sNDAs) dated and received March 23, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RETROVIR® (zidovudine) capsules, for oral use; RETROVIR® (zidovudine) syrup, for oral use and RETROVIR® (zidovudine) injection, for intravenous use.

These Prior Approval supplemental new drug applications provides for the following revisions to labeling:

- DOSAGE AND ADMINISTRATION, subsection 2.3 Prevention of Maternal-Fetal HIV-1 Transmission: Dosing recommendations regarding use of an appropriate-sized syringe in neonates was added
- USE IN SPECIFIC POPULATIONS, subsection 8.1 Pregnancy: Updated to include information on hyperlactatemia reported in neonates and infants exposed in utero or peri-partum to zidovudine-containing products
- PATIENT COUNSELING INFORMATION: Updated to include Dosage and Administration in Neonates regarding the use of an appropriate-sized syringe when administering syrup formulation
- “Note to Pharmacist” text was added to carton for syrup to align with changes in PI

APPROVAL & LABELING

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 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 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).

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the carton and immediate-container labels submitted on August 10, 2018, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 19910/S-045**." Approval of this submission by FDA is not required before the labeling is used.

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
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

POONAM MISHRA
09/10/2018
on behalf of Debra Birnkrant, MD