NDA 019655/S-059
NDA 019910/S-046
NDA 019951/S-037

SUPPLEMENT APPROVAL

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

Dear Mr. Hyatt:

Please refer to your supplemental New Drug Application(s) (sNDA) pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following products:

Supplemental Application	**Product Information**	**Submit and Received Date**
NDA 019655/S-059	Retrovir (zidovudine) Capsules, 100 mg	December 20, 2019
NDA 019910/S-046	Retrovir (zidovudine) Oral Solution, 10 mg/mL	December 20, 2019
NDA 019951/S-037	Retrovir (zidovudine) Injection, 200 mg/10 mL (10 mg/mL)	December 20, 2019

These "Changes Being Effected" supplemental new drug applications provide for the revision of the established name of the NDA 019910 drug product from Retrovir (zidovudine) Syrup to Retrovir (zidovudine) Oral Solution.

APPROVAL & LABELING

We have completed our review of these supplemental applications. 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 prescribing

information) 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 via 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 these supplemental applications, 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 enclosed carton and immediate container labels and carton and immediate container labels submitted on January 30, 2020, 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 *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 019910/S-046.**" Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Omolara Laiyemo, Regulatory Business Process Manager, at (240) 402 - 3842.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
Date: 6/18/2020 08:13:00AM
GUID: 508da72000029f287fa31e664741b577
Comments: concur; recommend approval from the standpoint of CMC