



DA 019951/S-039 N

APPROVAL LETTER

ViiV Healthcare Co
Attention: Chris Musteikis
CMC Regulatory Director
410 Blackwell Street
Durham, C 27701

Dear Mr. Musteikis:

Please refer to your Supplemental New Drug Application (s DA) dated and received N September 29, 2023, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Retrovir (zidovudine) injection, 200 mg/10 mL (10 mg/mL).

We acknowledge receipt of your amendment dated July 17, 2024, which constituted a complete response to our January 26, 2024, action letter. N

This Prior Approval supplemental new drug application provides for revision to the drug product container closure system to change the rubber stopper from (b) (4)

APPROVAL & LABELING N

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.

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>.

Information on submitting L files using eLIT 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/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/UCM07292.pdf>.

The L 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 14.50(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 CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels and carton and container labels submitted on October 21, 2024, 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 – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission “**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 019951/S-039.**” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 14.80 and 14.81.

If you have any questions, call Omolara Oyinlola Adeyemi, Regulatory Business Process Manager, at (240) 402 842.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.

Supervisor

Division of Product Quality Assessment XI

Office of Product Quality Assessment II

Office of Pharmaceutical Quality

Center for Drug Evaluation and Research

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Enclosures:

Content of Labeling s

Carton and Container Labeling s



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