



NDA 19655/S-56  
NDA 19910/S-43  
NDA 19951/S-34

## SUPPLEMENT APPROVAL

ViiV Healthcare Company  
Attention: Stephen Hyatt, RAC  
Senior Associate, 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 Applications (sNDAs) dated March 30, 2017, received March 30, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for RETROVIR<sup>®</sup> (zidovudine) capsules, 100 mg, RETROVIR<sup>®</sup> (zidovudine) syrup, 10 mg per mL, and RETROVIR<sup>®</sup> (zidovudine) injection, 10 mg per mL.

These “Changes Being Effected” supplemental new drug applications propose the following changes to labeling:

- To correct the language related to Antiretroviral Pregnancy Registry (APR) birth defect rates in Section 8.1 Pregnancy
- To add revised “How Supplied” information for Retrovir Injection in Section 16 and revised carton/container labeling for consistency

### **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 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 enclosed carton and immediate container 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 (June 2008)*.

Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 19951/S-034.**” 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 Christian Yoder, Regulatory Project Manager, at (240) 402-9990 or (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

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**ENCLOSURES:**

Content of Labeling  
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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POONAM MISHRA  
04/10/2017