NDA 020977/S-35
NDA 020978/S-38

SUPPLEMENT APPROVAL

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

Dear Mr. Pace:

Please refer to your supplemental new drug applications (sNDA) dated and received on May 18, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ziagen (abacavir) tablets and Ziagen (abacavir) oral solution.

These prior approval supplemental new drug applications provide for the following changes to the Ziagen US Prescribing Information (USPI):

- Updates to the DRUG INTERACTIONS and CLINICAL PHARMACOLOGY sections with information regarding coadministration with riociguat
- Corresponding changes to the Medication Guide
- Updates to the USE IN SPECIFIC POPULATIONS section to provide the most current information from the Antiretroviral Pregnancy Registry.

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are 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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (Prescribing Informationb and Medication Guide), with the addition of any labeling changes in

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, 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 Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), 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).

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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 Alicia Moruf, PharmD, MPH, RAC-US Regulatory Project Manager, at 301-796-3953.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information
    - Medication Guide
    - Warning Card

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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
11/24/2020 01:04:19 PM
on behalf of Division Director