



NDA 204790/S-13

**SUPPLEMENT APPROVAL**

ViiV Healthcare Company  
c/o GlaxoSmithKline  
Attention: Jeffrey S. Troughton, MS, RAC  
Director, Global Therapeutic Group Regulatory Affairs  
Five Moore Drive, PO Box 13398  
5.5100.5B  
Research Triangle Park, NC 27709

Dear Mr. Troughton:

Please refer to your Supplemental New Drug Application (sNDA) dated September 28, 2016, received September 28 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TIVICAY<sup>®</sup> (dolutegravir) tablet, 50mg.

This “Changes Being Effected” supplemental new drug application proposes to add arthralgia and myalgia to the ADVERSE REACTIONS, Postmarketing Experience subsection and updates the CLINICAL STUDIES section with the correct pediatric age groups studied in the IMPAACT P1093 study.

**APPROVAL & LABELING**

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**WAIVER OF HIGHLIGHTS SECTION**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

**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, 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).

### **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 Karen Winestock, Chief, Project Management Staff, at (301) 796-0834 or (301) 796-1500.

Sincerely yours,

*{See appended electronic signature page}*

Debra Birnkrant, MD  
Director  
Division of Antiviral Products  
Office of Antimicrobial Products  
Center for Drug Evaluation and Research

ENCLOSURE:  
Content of Labeling

-----  
**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
-----

/s/  
-----

POONAM MISHRA  
03/27/2017