



NDA 204790/S-005

SUPPLEMENT APPROVAL

ViiV Healthcare Company
c/o GlaxoSmithKline
Attention: Caroline J. Diaz, MA
Manager Infectious Diseases, Global Regulatory Affairs
Five Moore Drive, 5.5100.5B
Research Triangle Park, NC 27709

Dear Ms. Diaz:

Please refer to your Supplemental New Drug Application (sNDA) dated February 06, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TIVICAY (dolutegravir) tablets, 50mg.

We acknowledge receipt of your amendments dated April 21, 2105, May 08, 2015, June 08, 2015, July 20, 2015, July 29, 2015, and July 31, 2015.

This “Prior Approval” supplemental new drug application proposed the following changes:

- To update the labeling with drug-drug interaction information for:
 - carbamazepine, and metformin based on clinical trial results;
 - oxcarbazepine based on modeling and simulation data;
 - etravirine without concomitant use of certain boosted protease inhibitors based on modeling and simulation data; and
 - dolutegravir as a substrate of human OATP1B1, OATP1B3 and OCT1 transporters based on in vitro data.
- To remove telaprevir information because it is no longer marketed nor distributed in the United States.

APPROVAL & LABELING

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 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 patient package insert), with the addition of any labeling changes in pending “Changes Being Effectuated” (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 includes 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 Sohail Mosaddegh, PharmD, Regulatory Project Manager, at (301) 796-4876 or (301) 796-1500.

Sincerely yours,

{See appended electronic signature page}

Poonam Mishra, MD, MPH
Deputy Director for Safety
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURES:

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
08/05/2015