



NDA 21548/S-041
NDA 22116/S-025

SUPPLEMENT APPROVAL

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

Dear Mr. Pace:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received September 28, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LEXIVA (fosamprenavir calcium) tablets and LEXIVA (fosamprenavir calcium) oral suspension.

These Prior Approval sNDAs provide for the following revisions to labeling:

- **DOSAGE AND ADMINISTRATION** (subsection 2.2): Information regarding dosing in pregnant women was added.
- **CONTRAINDICATIONS** (Section 4): Lomitapide was added. In addition, contraindicated drugs were removed from Table 2, listed in bulleted format, and cross-referenced and described in more detail under **DRUG INTERACTIONS** (Section 7, Table 6).
- **DRUG INTERACTIONS** (subsection 7.1): Addition of several enzymes that ritonavir appears to induce.
- **DRUG INTERACTIONS** (subsection 7.2): Addition of information on potential drug interaction with antineoplastics and antacids; fentanyl was added to Narcotic analgesics and disopyramide was added to Antiarrhythmics (Table 6).
- **USE IN SPECIFIC POPULATIONS** (subsection 8.1): Addition of pharmacokinetics, safety and pregnancy outcomes data from a clinical trial in HIV-1 infected pregnant women.
- **CLINICAL PHARMACOLOGY** (subsection 12.3): Addition of pharmacokinetics data in pregnant women.
- **PATIENT INFORMATION** leaflet: Ergonovine and lomitapide were added to the list of medications that should not be taken with Lexiva.

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 ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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, 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 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion (OPDP)
5901-B Ammendale Road
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf>).

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>.

Information and Instructions for completing the form can be found at

<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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 Elizabeth Thompson, MS, Senior Program Management Officer,
at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

Content of Labeling
Prescribing Information
Patient Package Insert

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
03/28/2019 01:39:13 PM
on behalf of Debra Birnkrant