

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

208984Orig1s000

022128Orig1s017

Trade Name: SELZENTRY

Generic or Proper Name: maraviroc

Sponsor: ViiV Healthcare Company

Approval Date: November 4, 2016

Indication: SELZENTRY is indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in patients 2 years of age and older weighing at least 10 kg.

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208984Orig1s000

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APPROVAL LETTER



NDA 208984
NDA 22128/S-17

**NDA APPROVAL
SUPPLEMENT APPROVAL**

ViiV Healthcare Company
c/o GlaxoSmithKline
Attention: Mark Baumgartner
Sr. Director, Global Regulatory Affairs
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709-3398

Dear Mr. Baumgartner:

Please refer to your New Drug Application (NDA) dated May 6, 2016 received May 6, 2016, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SELZENTRY[®] (maraviroc) oral solution 20 mg/ml. We also refer to your Supplemental New Drug Application (sNDA) dated May 6, 2016 received May 6, 2016 submitted under section 505(b) of the FDC for SELZENTRY[®] (maraviroc) 25 mg, 75 mg, 150mg and 300mg tablets.

The Original NDA and Prior Approval supplemental NDA provide for the following:

- Use of SELZENTRY in combination with other antiretroviral agents for the treatment of only CCR5-tropic HIV-1 infection in patients 2 years of age and older weighing at least 10 kg
- 20 mg/mL oral solution
- Two lower dose strength tablets: 25 mg and 75 mg
- Labeling revisions to address the Pregnancy and Lactation Labeling Rule (PLLR).

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 text. This label was also updated to reflect the new PLLR labeling requirements.

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 (package insert, Medication Guide, and Instructions for Use). 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*, available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via 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 labels submitted on October 27, 2016 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 208984 and NDA 22128/S-17.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the products with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

MARKET PACKAGE

Please submit one market package of each drug product when it is available to the following address:

Andrew Gentles, PharmD, BCPS AQ-ID
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6211
10903 New Hampshire Avenue
Silver Spring, Maryland
*Use zip code **20903** if shipping via United States Postal Service (USPS).*
*Use zip code **20993** if sending via any carrier other than USPS (e.g., UPS, DHL, FedEx).*

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

NDA 208984

We are waiving the pediatric study age requirement from birth to less than 2 years of age because the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients in this age group **and** is not likely to be used in a substantial number of pediatric patients in this group.

NDA 208984 and NDA 22128/S-17

We note that you have fulfilled the pediatric study requirement for ages 2 to less than 18 years for these applications.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert, Medication Guide, and patient PI (as applicable) to:

OPDP Regulatory Project Manager
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
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>).

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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 Andrew Gentles, Regulatory Project Manager, at (240) 402-5708.

Sincerely,

{See appended electronic signature page}

Jeffrey S. Murray, MD, MPH
Deputy Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosures:
Content of Labeling
Carton and Container Labeling

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

/s/

JEFFREY S MURRAY
11/04/2016