NDA 202022/S-020
NDA 202022/S-022

SUPPLEMENT APPROVALS

Janssen Products, LP
c/o Janssen Research & Development, LLC
Attention: Kara L. Christie
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Kara L. Christie:

Please refer to your supplemental new drug applications (sNDA) dated and received July 25, 2023, and your amendments, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Edurant (rilpivirine) 25 mg tablet.

Supplement 20
This supplemental new drug applicaton expands the patient population to include HIV-1 infected, treatment-naïve pediatric patients with HIV-1 RNA less than or equal to 100,000 copies/mL, who are 2 to less than 12 years of age and weigh at least 25 kg to <35 kg. This supplemental new drug application contained data from Study TMC278-TiDP38-C213 Cohort 2.

Supplement 22
This supplement updates the USPI with safety and pharmacokinetic information from Study TMC278HTX2002 in pediatric patients with HIV-1 infection and weighing at least 25 kg to <35 kg.

These supplements also provide updates to:

- USE IN SPECIFIC POPULATIONS, Lactation, section with the updated breastfeeding recommendations and information regarding the presence of rilpivirine in human milk

- The Patient Package Insert (PPI) and container labels to be consistent with the changes made to the USPI.

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 with minor editorial revisions listed below and reflected in the enclosed labeling.

- The following changes were made to the Recent Major Changes section:

  Indications and Usage, Treatment of HIV-1 in Treatment-Naïve Patients (1.1)

  Warnings and Precautions, Different Formulations are Not Substitutable (5.6)

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use) 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 *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 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

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

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).

CONTAINER LABELING

Submit final printed container labeling that is identical to the enclosed container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Container Labeling for approved NDA 202022/S-020 and NDA 202022/S-022**." Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), 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 in pediatric patients unless this requirement is waived, deferred, or inapplicable

We note that you have fulfilled the pediatric study requirement for ages 2 to less than 12 years of age for this application.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated July 25, 2023, containing the final report for the following postmarketing requirements listed in the January 31, 2019, postapproval postmarketing requirement letter.

1982-3 Conduct a study in HIV-1 infected patients 2 to 12 years of age who are either treatment naïve with baseline HIV RNA <100,000 copies/mL or who are virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable antiretroviral regimen at the time of enrollment, to assess the pharmacokinetics, safety and tolerability, and antiviral activity of rilpivirine. Study participants must be monitored for a minimum of 24 weeks to assess durability of antiviral response.

We have reviewed your submission and conclude that the above requirement was fulfilled.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

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 FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, call London Harrison, MBEE, Regulatory Project Manager, at (301) 348-3926.

Sincerely,

{See appended electronic signature page}

Yodit Belew, MD
Associate Director for Therapeutic Review
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
- Container Labeling

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/

YODIT BELEW
03/15/2024 06:44:55 PM