NDA 219016/Original 1

**NDA APPROVAL**

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 new drug application (NDA) dated and received September 15, 2023, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Edurant PED (rilpivirine) 2.5 mg tablet, for oral suspension.

NDA 219016 provides for the use of Edurant PED (rilpivirine) 2.5 mg tablet, for oral suspension for the following indications which, for administrative purposes, we have designated as follows:

- NDA 219016/Original-1 – Provides for the use of Edurant PED in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve pediatric patients with HIV-1 RNA less than or equal to 100,000 copies/mL who are 2 years of age and older and weigh at least 14 kg to less than 25 kg.

(b) (4)

The subject of this action letter is NDA 219016/Original-1. (b) (4)

## APPROVAL & LABELING

We have completed our review of this application, as amended. It is 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

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

## CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and 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 Carton and Container Labeling for approved NDA 219016/Original-1**." Approval of this submission by FDA is not required before the labeling is used.

## DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Edurant PED (rilpivirine hydrochloride) 2.5 mg tablet for oral suspension shall be 24 months from the date of manufacture when stored at 20 to 25 °C.

[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.

## 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 reference the partial waiver granted in the January 31, 2019, Release From Postmarketing Requirement Letter for the pediatric study requirement for ages birth to less than 2 years of age.

This product is appropriately labeled for use in pediatric patients ages 2 to less than 18 years of age weighing greater than 25 kg.

We note that you have fulfilled the pediatric study requirement for ages 2 to 12 years of age weighing 14 kg to less than 25 kg for this application.

## 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]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

## REPORTING REQUIREMENTS

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

## COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for

[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

strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[6].

If you have any questions, contact 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
  - Instructions for Use
- Carton and Container Labeling

[6] https://www.uspnf.com/

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**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.**

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/s/

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