Dear Ms. Monshizadegan:

Please refer to your Supplemental New Drug Application (sNDA), received November 1, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Edurant (rilpivirine) 25 mg tablet.


This Prior Approval supplemental new drug application proposes the following:
- Update the package insert with drug-drug interaction information between rilpivirine and rifabutin or metformin
- To remove rifabutin information from the CONTRAINDICATIONS section of the package insert
- Update the ADVERSE REACTIONS, Clinical Trials Experience section of the package insert with revised adrenal function and lipid values
- Update the patient package insert with information about rifabutin

**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 agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

**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 the 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/Drugs/GuidanceComplianceRegulatoryInformation/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).

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 package insert(s) to:

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

You must submit final promotional materials and package insert(s), 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/opacom/morechoices/fdaforms/cder.html;
instructions are provided on page 2 of the form. 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 Sohail Mosaddegh, PharmD, Regulatory Project Manager, at
(301) 796-4876 or (301) 796-1500.

Sincerely yours,

{See appended electronic signature page}

Kendall Marcus, MD
Associate Director of Safety
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:

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/

KENDALL A MARCUS
05/01/2014