DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21976/S-43
NDA 202895/S-17

SUPPLEMENT APPROVAL

Janssen Products, LP
Attention: Karen Gerry, BsC
Associate Director, Global Regulatory Affairs
1125 Trenton-Harbourton Road
Titusville, NJ 08560

Dear Ms. Gerry:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received December 17, 2015 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PREZISTA® (darunavir) tablet, 75 mg, 150 mg, 600 mg, 800 mg (NDA 21976), and PREZISTA® (darunavir) oral suspension, 100 mg/mL (NDA 202895).

These Prior Approval supplemental new drug applications propose the following changes:

1. To update the DOSAGE AND ADMINISTRATION and CLINICAL PHARMACOLOGY, Pharmacokinetics sections of the labeling with data and results from a study investigating the use of darunavir during pregnancy and postpartum
2. To update USE IN SPECIFIC POPULATIONS sections 8.1 through 8.3 to be compliant with the "Pregnancy and Lactation Labeling Rule"

In addition, the Agency proposed the following changes:

3. To remove WARNINGS AND PRECAUTIONS, Resistance/Cross-Resistance subsection
4. To update DRUG INTERACTIONS section:
    a. Add clinical comments regarding the co-administration of omeprazole to Table 11.
    b. Create new section (section 7.4) to include drugs without clinically significant interaction with Prezista.
    c. Remove H_2 blockers and antacids because of the absence of supporting information to provide clinical recommendation regarding co-administration with Prezista.
    d. Remove telaprevir information from DRUG INTERACTIONS, Table 11 and CLINICAL PHARMACOLOGY, Table 17 because telaprevir is no longer marketed nor distributed in the United States.
5. To update CLINICAL PHARMACOLOGY section with addition of Figure 1 to display darunavir exposure changes in pregnant subjects by trimester.

6. To reformat and revise the PATIENT COUNSELING INFORMATION based upon the Agency's current standard.
7. To reformat and revise the PATIENT INFORMATION based upon the Agency's current standard.
8. To update the INSTRUCTIONS FOR USE.

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 and with the minor editorial revisions listed below.

- Under RECENT MAJOR CHANGES we changed

  WARNINGS AND PRECAUTIONS, (5.10) Removed (06/2016)

  to

  WARNINGS AND PRECAUTIONS, Resistance/Cross-Resistance (5.10) Removed 06/2016

WAIVER OF HIGHLIGHTS SECTION

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 package insert and 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/DrugsGuidanceComplianceRegulatoryInformation/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 these NDAs, 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(s) 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:

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 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/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 Nina Mani, Regulatory Project Manager, at (240) 402-0333.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
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/

DEBRA B BIRNKRANT
06/17/2016