DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21976/S-26
NDA 202895/S-2

SUPPLEMENT APPROVAL

Janssen Products, L.P.
Attention: Charles Zezza, PhD, MBA
Director, Global Regulatory Affairs
920 Route 202 S
Raritan, NJ 08869

Dear Dr. Zezza:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received May 3, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prezista® (darunavir) 75 mg, 150 mg, 400 mg, 600 mg tablets and 100 mg/mL oral suspension.

We acknowledge receipt of your amendment dated May 15, 2012.

These "Changes Being Effected" supplemental new drug applications proposed the following changes:

1. To add acute generalized exanthematous pustulosis to the WARNINGS AND PRECAUTIONS, *Severe Skin Reaction* and ADVERSE REACTIONS, *Postmarkeing Experience* sections of the labeling

2. To update the DRUG INTERACTIONS, *Established and Other Potentially Significant Drug Interactions* and CLINICAL PHARMACOLOGY, *Pharmacokinetics* with boceprevir drug-drug interaction information

3. To add VICTRELIS (boceprevir) to the "What should I tell my doctor before I take PREZISTA?" section of the labeling (patient package insert).

We have completed our review of these supplemental applications, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications 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).

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 Linda C. Onaga, MPH Regulatory Project Manager, at (301) 796-0759.

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/

KENDALL A MARCUS
06/01/2012