DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202379/S-007

SUPPLEMENT APPROVAL
FULLFILLMENT OF POSTMARKETING REQUIREMENT

Janssen Research & Development, LLC
Attention: Kelly Reid Johnson, MS, RAC
Associate Director, Regulatory Affairs
920 Route 202,
Raritan, NJ 08869

Dear Ms. Reid Johnson:

Please refer to your Supplemental New Drug Application (sNDA) dated March 12, 2013, received March 12, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zytiga® (abiraterone acetate) Tablets, 250 mg.

We acknowledge receipt of your amendments dated April 5, August 2, August 30, and September 9, 2013.

This "Prior Approval" supplemental new drug application provides for the following changes:

- Updates to the United States Prescribing Information (USPI) that recommend avoiding strong inducers of CYP3A4 based on data from the final study reports for drug-drug interaction trials evaluating the effect of a CYP3A4 inhibitor and a CYP3A4 inducer on the pharmacokinetics of Zytiga® (abiraterone acetate)
- Updates to the Overdosage section of the USPI to reflect limited human experience of overdose with Zytiga® (abiraterone acetate)

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.

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 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(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.

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

We have received your submission dated March 12, 2013, containing the final reports for the following postmarketing requirements listed in the April 28, 2011, approval letter.

1748-3 Conduct a drug-drug interaction trial to evaluate the effect of a strong CYP3A4 inducer (*e.g.*, rifampin) on the pharmacokinetics of abiraterone after an oral dose of abiraterone acetate. The proposed trial protocol must be submitted for review prior to trial initiation.

Final Protocol Submission:	October 2011
Trial Completion:	April 2013
Final Report Submission:	November 2013

1748-4 Conduct a drug-drug interaction trial to evaluate the effect of a strong CYP3A4 inhibitor (*e.g.*, ketoconazole) on the pharmacokinetics of abiraterone after an oral dose of abiraterone acetate. The proposed trial protocol must be submitted for review prior to trial initiation.

Final Protocol Submission:	October 2011
Trial Completion:	April 2013
Final Report Submission:	November 2013

We have reviewed your submission and conclude that the above requirements are fulfilled.

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 Rajesh Venugopal, Regulatory Project Manager, at (301) 796-4730.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Deputy Division Director
Division of Oncology Products 1
Office of Hematology and Oncology 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/

AMNA IBRAHIM
09/12/2013