



NDA 202379/S-004 PMR 1748-1

**SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING
REQUIREMENT**

Janssen Biotech, Inc.
Attention: Kelly Johnson Reid, MS, RAC
920 Route 202, P.O. Box 300
Raritan, NJ 08869-0602

Dear Ms. Johnson Reid:

Please refer to your Supplemental New Drug Application (sNDA) dated May 11, 2012, received May 11, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zytiga® (abiraterone acetate) Tablets.

We acknowledge receipt of your amendments dated May 22, July 16 and August 21, 2012.

This “Changes Being Effected” supplemental new drug application provides for updating Section 7.1, Drug Interaction, Effects of Abiraterone on Drug Metabolizing Enzymes and Section 12.3, Clinical Pharmacology, Pharmacokinetics, Drug Interactions to add information from a post-marketing study on Zytiga on inhibiting the hepatic drug-metabolizing enzyme CYP2C8.

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 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).

We have received your submission dated March 14, 2012, containing the final report for the following postmarketing requirement listed in the April 28, 2011 approval letter.

- 1748-1 Perform an in vitro screen to determine if abiraterone is an inhibitor of human CYP2C8. Based on results from the in vitro screen, a clinical drug-drug interaction trial may be needed.

We have reviewed your submission and conclude that the above requirement was fulfilled.

We remind you that there are postmarketing requirements listed in the April 28, 2011 approval that are still open.

If you have any questions, call Amy Tilley, Regulatory Project Manager, at (301) 796-3994.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Oncology Products 1
Office of Hematology and Oncology 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/

AMNA IBRAHIM
09/17/2012