CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 202379/S006

Trade Name: Zytiga

Generic Name: abiraterone acetate

Sponsor: Janssen Biotech, Inc.

Approval Date: June 17, 2013

Indication: ZYTIGA is a CYP17 inhibitor indicated in combination with prednisone for the treatment of patients with metastatic castration resistant prostate cancer.

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APPLICATION NUMBER:

NDA 202379/S006

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APPLICATION NUMBER:

NDA 202379/S006

APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202-379/S-006

APPROVAL LETTER

Janssen Biotech, Inc. c/o Janssen Research & Development, LLC
Attention: Jennifer Wilkinson
Associate Director Regulatory Affairs
1125 Trenton Harbourton Road
Titusville, NJ 08560

Dear Ms. Wilkinson:

Please refer to your Supplemental New Drug Application (sNDA) dated December 17, 2012, received December 17, 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 amendment dated May 21, 2013.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a change in the (b) (4)

We have completed our review of this supplemental new drug application, as amended. This supplement is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Yvonne Knight, Regulatory Project Manager, at (301) 796-2133.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch III, Division of New Quality Assessment I
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

NALLAPERUM CHIDAMBARAM
06/17/2013
for Dr. Hasmukh Patel

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 202379/S006

CHEMISTRY REVIEW(S)

Review of Chemistry, Manufacturing, and Controls

Clinical Review Division: Division of Oncology Products

NDA #: 20-2379 **CHEM. REVIEW #:** 1 **REVIEW DATE:** 05/28/13

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE	DUE DATE
N 202379 / S-006 (CBE)	12/17/12	12/17/12	02/05/13	06/17/13

NAME & ADDRESS OF APPLICANT: Janssen Biotech, Inc.
c/o Janssen Research & Development, LLC
800/850 Ridgeview Drive Route 202
Horsham, PA 19044

DRUG PRODUCT NAME

Proprietary: ZYTIGA Tablets
Nonproprietary/USAN: Abiraterone acetate

PHARMACOLOGICAL CATEGORY/INDICATION: In combination with prednisone for treatment of metastatic castration-resistant prostate cancer in patients who have received prior chemotherapy containing (b) (4)

DOSAGE FORM: Tablet

STRENGTHS: 250mg Abiraterone acetate/tablet

ROUTE OF ADMINISTRATION: Oral

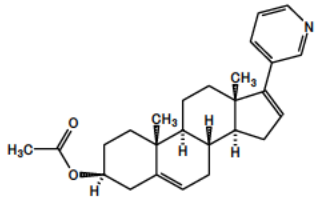
DISPENSED: Rx

PACKAGE SIZES:

SPECIAL PRODUCTS: ☐ Yes ☒ No (If yes, fill out the form for special products and deliver to TIA through team leader for data entry)

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL. WT:

Chemical Name: (3β)17-(3-pyridinyl)androsta-5,16-dien-3-yl acetate
Molecular Wt.: 391.55
Molecular Formula: $C_{26}H_{33}NO_2$



ABIRATERONE ACETATE

SUPPORTING DOCUMENTS: Sponsor e-Mail dated 20-MAY-2013

RELATED DOCUMENTS: NA

CONSULTS: NA

REMARKS/COMMENTS:

This Changes-being-Effected supplement requests approval to change to the (b) (4)

(b) (4)

(b) (4)

[redacted]

CONCLUSIONS & RECOMMENDATIONS: The CMC information presented in the submission to support the requested change is acceptable. The supplement is recommended for APPROVAL.

cc: Orig. NDA 20-2379
DMIHP/Division File
DMIHP/CSO/Y.Knight

filename: n202379s.006.doc

Allan Fenselau, Ph.D., Review Chemist

DRAFT SUPPLEMENT LETTER

There are no CMC–specific deficiencies.

3 Pages Immediately Following Withheld - b(4)

Reference ID: 3315005

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/s/

ALLAN H FENSELAU
05/28/2013

HASMUKH B PATEL
05/28/2013

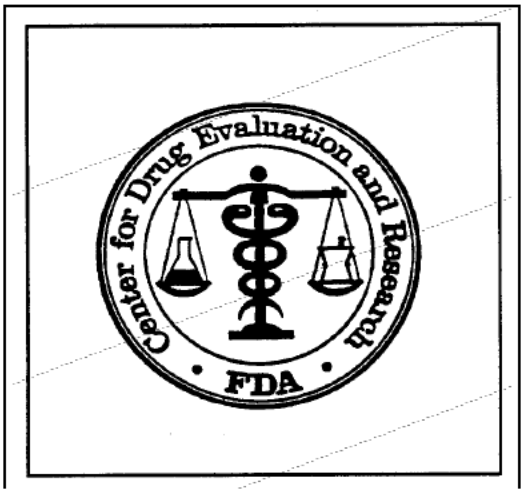
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 202379/S006

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

FACSIMILE TRANSMISSION
RECORD



From: Yvonne Knight

Office of New Drug Quality Assessment
Division of Post-Marketing Evaluation

Phone 301-796-2133
Fax 301-796-9748

Date: May 13, 2013 .

To:

Name Ms. Kelly Johnson Reid
Company Janssen Research & Development, LLC
City Raritan, NJ 08869 or Fremont, CA 94555 .

Phone: 908-927-3137
FAX: 908-526-5059 or 510-248-2456
e-Mail: kjohnso6@its.jnj.com

Number of Pages (INCLUDING COVER PAGE) 2 .

Subject: NDA#202379/S-006

Ms. Reid:

NDA 202379 / S-006

The following issue came up in reviewing the supplement that requests approval to change to the (b) (4) Please respond with an official amendment to this supplement by Monday, May 27, 2013 (or earlier). Let us know if this deadline cannot be met. In addition, a copy of your **official** response submitted directly to me by fax, overnight delivery, or e-mail [yvonne.knight@fda.hhs.gov] will expedite review of your request. If you have any questions about this matter or any other points in need of clarification, just call me (301-796-2133).

Thank you.

Yvonne Knight
Regulatory Health Project Manager

Reference ID: 3316997

These comments are being provided to you prior to completion of our review of the application to give you preliminary notice of issues that have been identified. These comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and are subject to change as the review of your application is finalized. In addition, we may identify other information that must be provided prior to approval of this application. If you choose to respond to the issues raised in this letter during this review cycle, depending on the timing of your response, we may or may not be able to consider your response prior to taking an action on your application during this review cycle.

NOTE: If your response can be found in the contents of your submission, just cite those sections of the submission that are relevant to the issue under consideration. Otherwise, **please provide the appropriate information as an official amendment to the submission. At the same time that an official response is sent to the Ammendale Road address, send me a copy of your official response by fax, e-mail or overnight delivery. The preferred method is by e-mail; all methods will expedite review of your request**. In your amendment Cover Letter refer to the date on which this information was requested.

Chemist's Concerns

1. In your correspondence with the Agency (dated 15-SEP-2011), you (b) (4)

(b) (4)

Please telephone (301) 796-2133 IMMEDIATELY if re-transmission is necessary.

THIS DOCUMENT IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEDGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.
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/s/

YVONNE L KNIGHT
05/31/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 202379/S-006

CBE SUPPLEMENT – ACKNOWLEDGEMENT

Janssen Research & Development, L.L.C.
On behalf of Janssen Biotech, Inc.
Attention: Steven Rabin, Ph.D.
Manager, Global CMC Regulatory Affairs
6500 Paseo Padre Parkway
Fremont, CA 94555

Dear Dr. Rabin:

We have received your Supplemental New Drug Application (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA or the Act) for the following:

NDA NUMBER: 202379

SUPPLEMENT NUMBER: S-006

PRODUCT NAME: Zytiga® (abiraterone acetate) Tablets

DATE OF SUBMISSION: December 17, 2012

DATE OF RECEIPT: December 17, 2012

This supplemental application, submitted as a "Changes Being Effected in 30 days" supplement, provides for a change to the (b) (4)

The application has been filed in accordance with 21 CFR 314.101(a).

The user fee goal date is June 17, 2013.

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Oncology Products I
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have any questions, call Deborah Mesmer, Regulatory Project Manager, at (301) 796-4023.

Sincerely,

{See appended electronic signature page}

Deborah M. Mesmer, M.S.
Regulatory Health Project Manager for Quality
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

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/s/

DEBORAH M MESMER
03/26/2013