CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202379Orig1s000

CHEMISTRY REVIEW(S)

ONDQA Division Director's Memo
NDA 202379, ZYTIGA (abiaterone acetate) 250 mg tablets
Date: April 08, 2011

Introduction

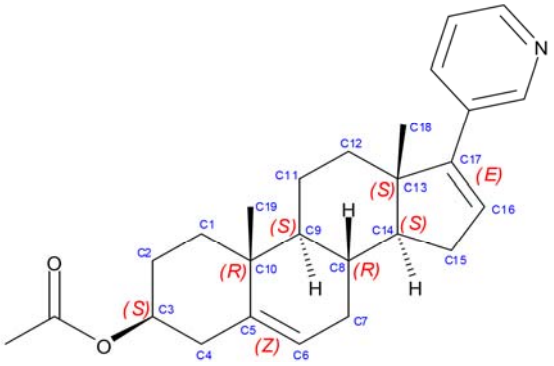
ZYTIGA tablets are indicated for the treatment of metastatic prostate cancer in resistant disease. Usual dosing is 1000 mg (as four tablets) taken once daily with food in combination with prednisone taken as a separate drug product.

Adminstrative

Supported by (b) (4) and six DMFs. The original NDA was received 20-DEC-2010 from Centocor Ortho Biotech, Inc. and was given Priority review status. A total of eight CMC, Biopharm, and labeling amendments were reviewed by ONDQA. All consults are acceptable including DMEPA for Tradename (14-MAR-2011) and EES (overall acceptable 04-APR-2011)
ONDQA recommends approval from the CMC perspective.

Drug Substance: abiraterone acetate

Chemical Name:
(3β)-17-(3-pyridinyl)androsta-5,16-dien-3-yl acetate
Structural Formula, Molecular Formula and Molecular Weight:



Molecular Formula:	$C_{26}H_{33}NO_2$
Molecular Weight:	391.55

Abiraterone acetate is a prodrug of the active abiratone. (b) (4)

(b) (4)

(b) (4) The approved

(4)

Drug Product: ZYTIGA 250 mg tablets

Abiraterone Acetate 250 mg, immediate release, uncoated tablets are white to off-white, oval-shaped, debossed with AA250 on one side. In addition to 250 mg abiraterone acetate, each tablet contains the following compendial inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulfate, magnesium stearate and colloidal silicon dioxide. All inactive ingredients are free from adventitious agents and compatible with abiraterone acetate. Drug loading is approximately (b) (4)

The container closure system consists of a 150-cc white HDPE bottle with child resistant closure and foil induction seal. The information on the container closure system is referenced in the Drug Master Files. All these DMFs are adequate to support the NDA.

Recently, the dissolution specification was approved as Q (b) (4) in 30 minutes. The following comment was sent to the applicant today via letter:
"… FDA recommended that this specification be implemented immediately in the NDA. FDA also confirmed that the recommended specification can be reassessed following approval, at the Applicant's discretion and in conformance with all applicable regulations."

CONVEY THE COMMENT BELOW TO APPLICANT IN ACTION LETTER:
A shelf-life of 12 months at 20°C to 25°C (68°F to 77°F) with excursions permitted to 15°C to 30°C (59°F to 86°F) [USP Controlled Room temperature] is approved.

Thank you.

Rik Lostritto, Ph.D., Director, ONDQA Division I.

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/s/

RICHARD T LOSTRITTO
04/08/2011

NDA 202379

ZYTIGA™
(abiraterone acetate) tablets 250 mg

Centocor Ortho Biotech, Inc.
Unit of Cougar Biotechnology, Inc
A Wholly-Owned Subsidiary of Johnson and Johnson

Debasis Ghosh, M.Pharm., Ph.D.

Product Quality Reviewer

Office of New Drug Quality Assessment
Division of New Drug Quality Assessment I
Branch II

CMC REVIEW OF NDA 202379
For the Division of Drug Oncology Products (HFD-150)

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CMC Review Data Sheet

1. NDA 2020379

2. REVIEW #: 1

3. REVIEW DATE: 31-Mar-2011

4. REVIEWER: Debasis Ghosh, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
Original IND 71023 submission/SD007	19-Dec-2005
(b) (4) SN002/SD0010	23-Feb-2006
SN0010/SD0071	30-Jan-2008
SN0048/SD0073	06-Feb-2008
CMC EOP2 Meeting	04-Mar-2008
CMC Review of IND71023/SD0300 by Joyce Z Crich	13-May-2009
Pre-NDA CMC Meeting Information Package	23-Oct-2009
CMC pre-NDA meeting minutes	06-Jan-2010
(b) (4) (b) (4) /SD0562	12-Mar-2010
CMC Review of IND71023/SD526 by Mike Adams	10-May-2010

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	DARRTS SD Number	Document Date
Original NDA Submission (0000)	1	20-Dec-2010
Amendment 0003 (CMC)	4	27-Jan-2011
Amendment 0007 (labeling)	8	22-Feb-2011
Amendment 0009 (CMC)	10	07-Mar-2011
Amendment 0010 (labeling)	11	14-Mar-2011
Amendment 0011 (Biopharm/CMC)	12	21-Mar-2011
Amendment 0012 (labeling)	13	28-Mar-2011

CMC Review Data Sheet

7. NAME & ADDRESS OF APPLICANT:

Name:	Centocor Ortho Biotech, Inc. Unit of Cougar Biotechnology, Inc.
Address:	10990 Wilshire Blvd., Suite #1200, Los Angeles, CA 90024-3913
Representative:	Christine M. Woods, Associate Director for Regulatory Affairs
Telephone:	310-943-8040 Ext 144

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: ZYTIGA™ (DMEPA accepted the name on 14-Mar-2011)
b) Non-Proprietary Name: Abiraterone Acetate
c) Code Name/# (ONDQA only): N/A
d) Chem. Type/Submission Priority (ONDQA only):

- Chem. Type: 1 (new molecular entity)
- Submission Priority: P

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: Anti-cancer

11. DOSAGE FORM: Immediate Release Tablet

12. STRENGTH/POTENCY: 250 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: __√__Rx ___OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

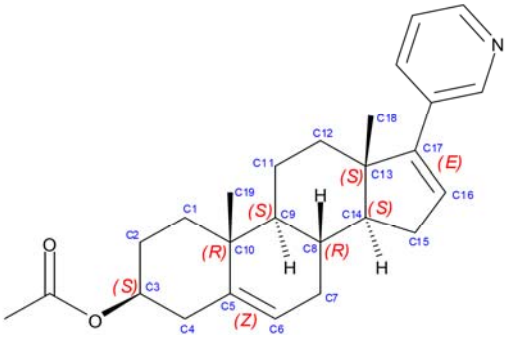
_____SPOTS product – Form Completed

__x___Not a SPOTS product

CMC Review Data Sheet

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Chemical Name:
(3β)-17-(3-pyridinyl)androsta-5,16-dien-3-yl acetate
Structural Formula, Molecular Formula and Molecular Weight:



Molecular Formula: $C_{26}H_{33}NO_2$

Molecular Weight: 391.55

CMC Review Data Sheet

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE[1]	STATUS[2]	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	Type III		(b) (4)	4	Adequate	NA	LOA: 01-Dec-2009; last reviewed by Yong De Lu on 13-Apr-2009
	Type III			3	Adequate	NA	LOA: 06-Dec-2010; last reviewed by Caroline Strasinger on 07-Jul-2010 and found to be (b) (4)
	Type III			4	Adequate	NA	LOA: 01-Dec-2009; last reviewed by Yong De Lu on 13-Apr-2009.
	Type III			3	Adequate	NA	LOA: 06-Dec-2010; last reviewed by Rajiv Agarwal on 03-Oct-2007 for (b) (4)
	Type III			3	Adequate	NA	LOA: Dec 06, 2010; last reviewed by Caroline Strasinger on 07-Jul-2010 and found to be adequate for (b) (4)
	Type II			1	Adequate	25-Mar-2011	LOA: Jan 05, 2011; Reviewed by Debasis Ghosh for NDA 202379

[1] Action codes for DMF Table:
1 – DMF Reviewed.
Other codes indicate why the DMF was not reviewed, as follows:

2 –Type 1 DMF
3 – Reviewed previously and no revision since last review
4 – Sufficient information in application
5 – Authority to reference not granted
6 – DMF not available
7 – Other (explain under "Comments")

[2] Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: None

18. STATUS:

ONDQA:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER/SIGNERS
Biometrics	N/A	N/A	N/A
EES	Pending	Pending	N/A
Pharm/Tox	Pending	Pending	Robeena Aziz; Robert Dorsam
Biopharm	Complete Response	3/30/2011	Tien Mien Chen; Patrick J. Marroum
LNC	N/A		
Methods Validation	N/A, according to the current ONDQA policy	N/A	N/A
DMEPA*	'acceptable'	14-Mar-2011	Jibril Abdus-Samad; Todd D. Bridges; Carol Holquist
EA	N/A	N/A	N/A
Microbiology	N/A	N/A	N/A

*DMEPA: Division of Medication Error Prevention and Analysis

The CMC Review for NDA 202-379

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From the perspective of Chemistry, Manufacturing and Controls (CMC), this NDA cannot be recommended for 'approval' from a CMC standpoint until the following three issues are addressed and completely resolved:

- An overall "acceptable" recommendation has not yet been issued by the Office of Compliance
- As per the 3/30/2011 memorandum, the ONDQA Biopharmaceutics reviewer identifies one outstanding deficiency related to dissolution acceptance criteria.
- Final labeling needs to be negotiated.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

II. Summary of CMC Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

(1) Drug Substance

Abiraterone acetate, the drug substance, is an acetyl ester of abiraterone. It is a pro-drug of the active metabolite abiraterone. Abiraterone acetate is converted in vivo to abiraterone which selectively inhibits the enzyme CYP17. Abiraterone acetate is designated chemically as (3β)-17-(3-pyridinyl)androsta-5,16-dien-3-yl acetate. It is a white to off-white, non-hygroscpic, crystalline powder. It is freely soluble in organic solvents like tetrahydrofuran and dichloromethane but practically insoluble in water. It shows some solubility in 0.1N HCl. It should be noted that abiraterone acetate contains a (b) (4). The dissociation constant (pKa) of abiraterone acetate is 5.19. It indicates that most of the abiraterone acetate will be soluble in stomach pH and most of the drug will be absorbed in the unionized form in the intestine at higher pH.

The partition coefficient (log P) value of abiraterone acetate is 5.12 indicating high lipophilicity. Based on low aqueous solubility and low permeability thru the cells in GI tract, the drug substance is considered BCS Class IV.

(b) (4) During the pre-NDA meeting, the Agency indicated that based on the principles of FDA Guidance (Guidance for Industry, Environmental Assessment of Human Drug and Biologics 1998), no environmental assessment is necessary if the (b) (4)

(b) (4) is proposed for the commercial development

Based on the stability data for drug substance, (b) (4) months retest period is granted when abiraterone acetate is stored in the proposed packaging conditions at 15°C to 30°C, protected from light.

(2) Drug Product

Drug product is Abiraterone Acetate 250 mg, immediate release, uncoated, orally administered tablet. It is white to off-white, oval-shaped, debossed with AA250 on one side. In addition to 250 mg abiraterone acetate, it contains compendial inactive ingredients generally used for tablet preparation and no novel excipients. Inactive ingredients in the tablets are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, povidone, sodium lauryl sulfate, magnesium stearate and colloidal silicon dioxide. All inactive ingredients are free from adventitious agents and compatible with abiraterone acetate. Drug loading is (b) (4)

(b) (4) The product is packaged in a HDPE bottle (120-count) with child resistant closures. The drug product is manufactured and packaged in Canada. The inspection of this facility is pending.

The quality attributes of abiraterone acetate tablets include appearance, identification, assay, chromatographic purity, uniformity of dosage units, (b) (4) (b) (4) dissolution, and microbial limits. The specification for each quality attribute was justified. Based on Biopharm review (DARRTS 08-Mar-2011) a revised specification (Q (b) (4) at 30 minutes in lieu of Q= (b) (4) at 45 minutes) for dissolution is recommended (b) (4) .

The container closure system consists of a 150-cc white HDPE bottle with child resistant closure and foil induction seal. The information on the container closure system is referenced in the Drug Master Files. All these DMFs are adequate to support the NDA.

Based on the available stability data for Zytiga™, a shelf-life of 12 months at 20°C to 25°C (68°F to 77°F) with excursions permitted to 15°C to 30°C (59°F to 86°F) [USP Controlled Room temperature] is granted.

B. Description of How the Drug Product is Intended to be Used

Zytiga™ (abiraterone acetate) is 17-α-hydroxylase inhibitor indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer who have received prior chemotherapy containing docetaxel.

Zytiga™ 1000 mg (four 250 mg tablets) administered once daily without food in combination with prednisone 5 mg orally twice daily.

C. Basis for Approvability or Not-Approval Recommendation

Approval

(1) The applicant referenced part of the drug substance information in the DMF (b) (4) DMF holder provided satisfactory information to support the NDA.

(2) The applicant provided satisfactory information on the manufacturing, control and stability of the drug substance.

(3) The applicant provided satisfactory information on the manufacturing, controls and stability of the drug product.

Pending Issues:

(1) The EES report is pending. Until the manufacturing and testing facilities receive an overall acceptable recommendation, the application cannot be recommended for approval.

(2) Until the package insert and container/carton labeling issues are resolved, the application cannot be recommended for approval.

III. Administrative

A. Reviewer's Signature:
(See appended electronic signature page)

Debasis Ghosh, M.Pharm., Ph.D., Product Quality Reviewer, ONDQA

B. Endorsement Block:
(See appended electronic signature page)

Sarah Pope Miksinski, Ph.D., Branch Chief, Branch II, Division of New Drug Quality Assessment I (DNDQA I), ONDQA

Rik Lostritto, Ph.D., Division Director, Division of New Drug Quality Assessment I (DNDQA I), ONDQA

C. CC Block: entered electronically in DARRTS

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/s/

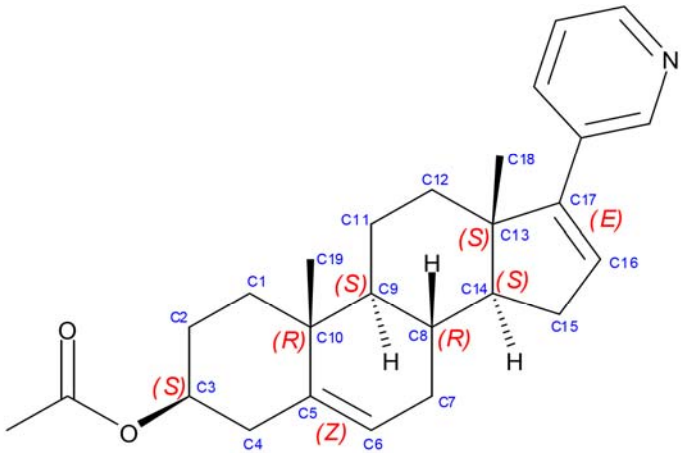
DEBASIS GHOSH
03/31/2011

SARAH P MIKSINSKI
03/31/2011

Date: 01-Feb-2011
To: NDA 202379
From: Debasis Ghosh, Ph.D. Product Quality Reviewer, Div 1, Br II, ONDQA
Through: Sarah Pope, Ph.D. Branch Chief, Div 1, Br II, ONDQA
Subject: NDA 202379: Consideration for Inspection of DS Manufacturing Site

The application (NDA 202379) was submitted on 20-Dec-2010 under 505(b)(1) by Centocor Ortho for the commercialization of Abiraterone Acetate, a New Molecular Entity (NME), as an anticancer agent. Drug product is Abiraterone Acetate Tablet containing (b) (4) Abiraterone Acetate as active ingredient and common inactive ingredients used in the tablet preparation. Abiraterone Acetate (b) (4)

Drug Substance:
Abiraterone Acetate, the drug substance, is a white to off-white, non-hygroscopic powder (b) (4) . Abiraterone Acetate may exist in (b) (4) (b) (4) (b) (4) is proposed for the commercial development.



Molecular Formula: $C_{26}H_{33}NO_2$

Molecular Weight: 391.55

Reviewer's Assessment of Risk:

1. Since the drug substance intermediate, (b) (4) is obtained from another manufacturer (b) (4) the quality of the drug substance intermediate will influence the quality of the drug substance. The quality of the drug substance intermediate may be affected by the change of supplier of the

starting material, alteration of synthesis method and inadequate control of carry-forward impurities.

2. [redacted] is considered a genotoxic impurity. Formation of [redacted] during the Abiraterone Acetate [redacted] is possible. Control of the formation and removal of [redacted] is an important part of quality management.

CMC Perspective Considerations for Inspection:

- The quality system should be capable of the internal Quality Management System (QMS) and Change control strategy to ensure the quality of the incoming materials.
- The quality system should be capable of the in-process controls to ensure the removal of all possible [redacted] during the synthesis and purification of the drug substance.

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/s/

DEBASIS GHOSH
02/11/2011
From CMC reviewer's perspective discussed DS site PAI related issues only.

SARAH P MIKSINSKI
02/14/2011

Initial Quality Assessment
Branch II
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment

OND Division:	**Division of Drug Oncology Products**
NDA:	**202-379**
Applicant:	**Centocor Ortho Biotech, Inc.**
Stamp Date:	**20 December, 2010**
PDUFA Goal Date:	**20 June, 2011 (Priority)**
Established Name:	**Abiraterone Acetate**
Trade Name	**ZYTIGA (proposed)**
Dosage Form and Strength:	**Tablet – 250 mg**
Route of Administration:	**Oral**
Indication:	**Indicated with prednisone for the treatment of metastatic (b) (4) (castration-resistant prostate cancer) in patients who have received prior chemotherapy containing a (b) (4)**
eCTD Reference for CMC	**eCTD.**
Regulatory Filing	**For 505 (b) (1)**
Related IND	(b) (4)
Assessed by:	**Haripada Sarker**

	Yes	No
ONDQA Fileability:	x	
Comments for 74-Day Letter:		x

Background Summary

The application introduces the drug as a new molecular entity. Abiraterone acetate is supplied as a tablet containing 250 mg of active ingredient for oral administration. (b) (4)

Several DS and DP CMC related issues were discussed in a CMC specific pre-NDA meeting dated October 23, 2009 (see meeting minutes in DARRTS). The issues involved starting material, analytical method, stability data, manufacturing process change etc. The NDA is submitted as per eCTD format.

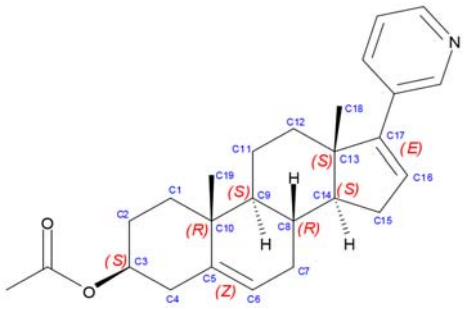
Drug Substance (DS)

(b) (4)

(b) (4)

(b) (4)

Chemical Name: (3β)-17-(3-pyridinyl)androsta-5,16-dien-3-yl acetate). The DS is identified with the following structure:



(b) (4)

DS manufacturing process controls and specifications are elaborated with justifications. Long-term and accelerated stability studies of abiraterone acetate drug substance are being conducted, under ICH recommended storage conditions, on the 3 primary registration batches produced according to the proposed commercial synthesis process. Based on the currently available stability data, a retest period of (b) (4) months is proposed to abiraterone acetate drug substance, when stored in the proposed packaging configuration. Storage conditions are: Store at 15–30 ºC.

DS Critical Issues

- Critical review of the Type II DMF (b) (4) submitted by (b) (4) (b) (4) abiraterone acetate.
- Verify the controls for starting material (b) (4). Also examine the need for environmental assessment of (b) (4) (b) (4)
- Verify the control strategy for DS genotoxic impurities including, (b) (4) and (b) (4)
- Verify the DS proposed retest period of (b) (4) months.

Drug Product (DP)
Abiraterone acetate 250-mg tablets have been developed as an orally administered, immediate-release uncoated tablet. The tablet is white to off-white oval shaped debossed with 'AA250'. The component and composition are shown in the following Table.

Component	Reference to Quality Standard[a]	Function	mg/tablet
Abiraterone Acetate	Company Standard	Active	250.00
Lactose Monohydrate	NF/Ph. Eur.		(b) (4)
Microcrystalline Cellulose	NF/Ph. Eur.		
Croscarmellose Sodium	NF/Ph. Eur.		
Povidone (b) (4)	USP/Ph. Eur.		
Sodium Lauryl Sulfate	NF/Ph. Eur.		
Colloidal Silicon Dioxide	NF/Ph. Eur.		
Magnesium Stearate	NF/Ph. Eur.		
(b) (4)	USP/Ph. Eur.		
Total Tablet Weight:			715.0

[a] Where multiple compendia are listed, the compendium applied is specific to the applicable region of the submission.

(b) (4)

NA = Not applicable

The proposed commercial container closure system, for the drug product, is a 150-cc high density polyethylene (HDPE) bottle with polypropylene child-resistant closure and foil induction seal (120-count). The DP is manufactured by (b) (4) Process validation will be performed prior to launch of the drug product for commercial use. The main DP manufacturing site is listed below:

Patheon, Inc.
2100 Syntex Court
Mississauga, Ontario, L5N 7K9
Canada

Batch analysis for DP batches representative of the final formulation, manufacturing process, and commercial facility are provided. Batch data provided in the table were generated at release, according to the specifications and tests in place at the time of testing. The corresponding section presents the justifications for the drug product specifications, along with the justification of why the (b) (4) (b) (4) specification is not included.

Registration stability for 6 batches of the drug product has been initiated for batches manufactured and packaged at the proposed commercial facility Patheon Inc. The registration drug product batches were manufactured (b) (4) Stability is conducted at ICH long-term and accelerated conditions in the proposed commercial container/closure system at Patheon.

Changes in Test Methods: (b) (4) were used to analyze the

DP registration stability batches. A new gradient HPLC method, (b) (4) was developed and validated for the identification and determination of abiraterone acetate and its related substances. To improve better separation of impurities, the new HPLC method was introduced for the related substances, (b) (4), and has the same method parameters as the drug substance method. Post approval stability protocol and stability commitment will be conducted by Patheon, Inc. The stability tests include Appearance, Assay, Chromatographic Purity and Dissolution.

All stability batches appear to meet the acceptance criteria after storage at 25 ºC/60% RH and 30 ºC/75% RH for 12 months and 40 ºC/75% RH for a period of 6 months. The appearance of the tablets remains unchanged at all conditions through the longest interval studied for each condition. A slight decrease in dissolution was observed for some of the batches stored at long-term and accelerated conditions during stability studies of the drug product. The dissolution results are within acceptance criteria under all conditions through the longest interval studied for each condition.

Based on 12 months available stability data on abiraterone acetate 250-mg tablets a (b) (4) months shelf-life is proposed when stored at room temperature. Applicant utilized ICH Q1E Evaluation of Stability Data, Appendix A decision tree.

Drug Product Critical Issues

- Check EES of DP sites for accuracy. File EES Exception Request if necessary for an expedited review clock.
- DMFs for container/closure system need to be reviewed for adequacy.
- Control of Polymorphic form and particle size in DP manufacturing.
- Specification for dissolution needs to be justified and input from biopharm reviewer is necessary.
- Justify the acceptability of the proposed (b) (4) months shelf-life for DP supported by only12 months real time stability when stored at room temperature.

Fileability Template

	Parameter	Yes	No	Comment
1	On its face, is the section organized adequately?	√		
2	Is the section indexed and paginated adequately?	√		
3	On its face, is the section legible?	√		
4	Are ALL of the facilities (including contract facilities and test laboratories) identified with full street addresses and CFNs?	√		
5	Is a statement provided that all facilities are ready for GMP inspection?	√		
6	Has an environmental assessment report or categorical exclusion been provided?	√		
7	Does the section contain controls for the drug substance?	√		
8	Does the section contain controls for the drug product?	√		
9	Has stability data and analysis been provided to support the requested expiration date?	√		Tentatively.
10	Has all information requested during the IND phase, and at the pre-NDA meetings been included?	√		CMC issues in pre-NDA meeting appeared

				to be addressed in the NDA.
11	Have draft container labels been provided?	√		
12	Has the draft package insert been provided?	√		
13	Has a section been provided on pharmaceutical development/ investigational formulations section?	√		
14	Is there a Methods Validation package?	√		
15	Is a separate microbiological section included?		√	Tablet formulation.
16	Have all consults been identified and initiated? (bolded items to be handled by ONDQA PM) HPLC assay on DP stability reported statistical analysis (ref. vol 1, p161).	√ √ √ √ √		Microbiology Pharm/Tox Biopharm Statistics (stability) OCP/CDRH/CBER LNC DMETS/DMEPA/ODS **EER**

Have all DMF References been identified? Yes (√) No ( )

DMF/IND Number	Holder	Description	LOA Included
DMF (b) (4) (Type II)	(b) (4)		Yes
DMF (b) (4) (Type III)			Yes
DMF (b) (4) (Type III)			Yes
DMF (b) (4) (Type III)			Yes
DMF (b) (4) (Type III)			Yes
DMF (b) (4) (Type III)			Yes

Comments and Recommendations

The application is fileable and no 74-Day Letter issue has been identified at this point. Facilities have been entered into EES for inspection. A single reviewer should be able to review this NDA, since the manufacturing process is not particularly complex. Note the potential for an expedited review clock for this NDA. If the review is expedited, an EES Exception Request should be filed as soon as possible.

Haripada Sarker CMC Lead	January 19, 2011 Date
Sarah Pope Miksinski, Ph.D. Branch Chief	January 19, 2011 Date

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

HARIPADA SARKER
01/19/2011

SARAH P MIKSINSKI
01/21/2011