

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

203415Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

07 August 2012

NDA: 203415/N-000

Drug Product Name

Proprietary:

Xtandi.

Non-proprietary:

Enzalutamide.

Review Number:

1.

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
21 MAY 2012	22 MAY 2012	25 MAY 2012	31 MAY 2012

Applicant/Sponsor

Name:

Medivation, Inc.

Address:

201 Spear St.

Third Floor

San Francisco, CA 94105

Representative:

Lynn Seely, MD

Telephone:

415-829-4106

Name of Reviewer:

John W. Metcalfe, Ph.D.

Conclusion:

Recommend approval.

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** 505 (b)(1) NDA.
2. **SUBMISSION PROVIDES FOR:** Marketing authorization.
3. **MANUFACTURING SITE:**
Catalent Pharma Solutions, LLC.
2725 Scherer Dr.
St. Petersburg, FL 33716
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
- Liquid filled soft gelatin capsule.
 - Oral.
 - 40 mg/capsule.
5. **METHOD(S) OF STERILIZATION:** The drug product is not sterile.
6. **PHARMACOLOGICAL CATEGORY:** The drug product is indicated for the treatment of patients with castration-resistant prostate cancer who have received docetaxel (b)(4).
- B. **SUPPORTING/RELATED DOCUMENTS:** None.
- C. **REMARKS:**
The subject NDA is submitted electronically in the CTD format.

File Name: N203415R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – NDA 203415/N-000 is recommended for approval on the basis of issues pertaining to product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – Not applicable.

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** - The fill material comprising the drug substance and excipients (b) (4) and packaged.
- B. Brief Description of Microbiology Deficiencies** – There are no microbiology deficiencies identified.
- C. Assessment of Risk Due to Microbiology Deficiencies** – Not applicable.

III. Administrative

- A. Reviewer's Signature** _____
John W. Metcalfe, Ph.D.
Senior Microbiology Reviewer
CDER/OPS/NDMS
- B. Endorsement Block** _____
Stephen E. Langille, Ph.D.
Senior Microbiology Reviewer
CDER/OPS/NDMS
- C. CC Block**
N/A

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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/

JOHN W METCALFE
08/07/2012

STEPHEN E LANGILLE
08/07/2012