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

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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. 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 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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Reference ID: 3170901
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/s/

JOHN W METCALFE  
08/07/2012

STEPHEN E LANGILLE  
08/07/2012