

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

201525Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

7 APRIL 2011

NDA: 201525

Drug Product Name

Proprietary: N/A

Non-proprietary: Docetaxel Injection

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
16 September 2010	17 September 2010	23 September 2010	4 October 2010

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Sandoz Inc.

Address: 506 Carnegie Center, Suite 400, Princeton, NJ 08540

Representative: Bernadette Attinger, Director of RA

Telephone: (609) 627-8865

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA 505(b)(2)
 - 2. SUBMISSION PROVIDES FOR:** A new parenteral drug product
 - 3. MANUFACTURING SITE:** Ebewe Pharma Ges.m.b.H.
Nfg.KG
Mondseestrasse 11
A-4866 Unterach, Austria
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile non-aqueous solution in a multi-use glass vial for intravenous infusion, 10mg/mL (20mg/2mL, 80mg/8mL, 160mg/16mL)
 - 5. METHOD(S) OF STERILIZATION:** (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Oncology
- B. SUPPORTING/RELATED DOCUMENTS:** Product Quality Microbiology review of DMF (b) (4) (DARRTS Final date 12 August 2010).
- C. REMARKS:** This was an eCTD submission

filename: N201525R1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is (b) (4)
- B. Brief Description of Microbiology Deficiencies** – N/A
- C. Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
Senior Review Microbiologist, OPS/NDMS
- B. Endorsement Block** _____
Stephen E. Langille, Ph.D.
Senior Review Microbiologist, OPS/NDMS
- C. CC Block**
N/A

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/s/

BRYAN S RILEY
04/08/2011

STEPHEN E LANGILLE
04/08/2011

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 201525

Applicant: Sandoz Inc.

Letter Date: 16 Sept. 2010

Drug Name: Docetaxel
Injection

NDA Type: 505(b)(2)

Stamp Date: 17 Sept. 2010

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		The submission was provided in the eCTD format.
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		The drug product is (b) (4)
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?	X		Translated versions were provided.
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: N/A

18 October 2010

Bryan S. Riley, Ph.D.
Senior Review Microbiologist

Date

Stephen E. Langille, Ph.D.
Senior Review Microbiologist

Date

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/s/

BRYAN S RILEY
10/21/2010

STEPHEN E LANGILLE
10/21/2010