

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-602

MICROBIOLOGY REVIEW

**Product Quality Microbiology Review
Review for HFD-150**

1 MAY 2003

NDA: 21-602

Drug Product Name

**Proprietary: VELCADE for injection
Non-proprietary: bortezomib
Drug Product Priority: S**

Review Number: 1

Subject of this Review

**Submission Date: 21 January 2003
Receipt Date: 21 January 2003
Consult Date: 29 January
Date Assigned for Review: 21 February 2003**

Submission History (for amendments only)

**Date(s) of Previous Submission(s): N/A
Date(s) of Previous Micro Review(s): N/A**

Applicant/Sponsor

**Name: Millenium Pharmaceuticals
Address: 75 Sidney Street; Cambridge, MA 02139
Representative: Robert Pietrusko
Telephone: 617-679-7000**

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

Conclusion: Recommended for Approval

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ON ORIGINAL**

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
 2. SUPPLEMENT PROVIDES FOR: N/A
 3. MANUFACTURING SITE: []
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: lyophilized powder for IV injection, 3.5 mg
 5. METHOD(S) OF STERILIZATION: Aseptic Fill
 6. PHARMACOLOGICAL CATEGORY: Multiple Myeloma
- B. SUPPORTING/RELATED DOCUMENTS: N/A
- C. REMARKS: This was an electronic submission in the CTD-Q.

filename: 21602.doc

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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 sterilized by filtration and aseptically filled.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product is manufactured using a validated aseptic process by a manufacturer of numerous small volume parenterals. Therefore, the drug product presents a minimal risk from the standpoint of product quality microbiology.

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. **CC Block**
N/A

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/s/

Bryan Riley
5/2/03 07:53:54 AM
MICROBIOLOGIST

Peter Cooney
5/2/03 10:18:10 AM
MICROBIOLOGIST

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