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
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
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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