

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-041

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

27 OCTOBER 2006

NDA: 22-041

Drug Product Name

Proprietary: Cyanokit

Non-proprietary: hydroxocobalamin

Drug Product Priority Classification: P

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
6/16/2006	6/19/2006	7/20/2006	7/28/2006

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: EMD Pharmaceutical

Address: 3211 Shannon Road, Suite 500, Durham, NC 27707

Representative: Elliott T. Berger

Telephone: 919-401-7107

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original New Drug Application
2. **SUBMISSION PROVIDES FOR:** A sterile drug product for injection
3. **MANUFACTURING SITE:** Merck Sante s.a.s.
Centre de production de Semoy
2 rue du Pressoir Vert
45400 Semoy
France
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile lyophilized powder for injection in a 250 mL glass vial with a gray _____ rubber stopper and _____ cap, for intravenous infusion, 2.5 g/vial, 2 vials per carton. **b(4)**
5. **METHOD(S) OF STERILIZATION:** _____
6. **PHARMACOLOGICAL CATEGORY:** treatment of cyanide poisoning
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** N/A

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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 _____ **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.
- B. **Endorsement Block** _____
James L. McVey
(Microbiology Team Leader)
- C. **CC Block**
N/A

5 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Bryan Riley
11/2/2006 01:15:13 PM
MICROBIOLOGIST

James McVey
11/2/2006 02:51:34 PM
MICROBIOLOGIST