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RESEARCH**

*APPLICATION NUMBER:*

**22-137**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

28 JUNE 2007

**NDA:** 22-137

**Drug Product Name**

**Proprietary:** N/A

**Non-proprietary:** Fludaribine Phosphate Injection

**Drug Product Priority Classification:** S

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

Letter	Stamp	Consult Sent	Assigned to Reviewer
11/22/2006	11/24/2006	1/17/2007	1/17/2007

**Submission History (for amendments only):** N/A

**Applicant/Sponsor**

**Name:** Ebewe Pharma Ges.m.b.H. Nfg.KG

**Address:** Mondseestrasse 11, 4866 Unterach, Austria

**Representative:** Elizabeth N. Dupras, RAC (B&H Consulting Services Inc.)

**Telephone:** 908-704-1691, ext 223

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

**Conclusion:** Recommended for Approval

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
  2. **SUBMISSION PROVIDES FOR:** Sterile injectable drug product
  3. **MANUFACTURING SITE:** EBEWE Pharma Ges.m.b.H Nfg.KG  
Mondseestrase 11  
4866 Unterach  
Austria
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile aqueous solution for intravenous administration in a — glass vial with — 50 mg/2 mL **b(4)**
  5. **METHOD(S) OF STERILIZATION:** — **b(4)**
  6. **PHARMACOLOGICAL CATEGORY:** Treatment of B-cell chronic lymphocytic leukemia
- B. **SUPPORTING/RELATED DOCUMENTS:** Review of DMF — (review dated 26 April 2006) **b(4)**
- C. **REMARKS:** This was a paper submission in the CTD format. Two volumes were provided for product quality microbiology review (Module 3 volumes 1.1 and 1.2).

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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

6 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

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Bryan Riley  
7/5/2007 08:01:40 AM  
MICROBIOLOGIST

James McVey  
7/5/2007 01:58:58 PM  
MICROBIOLOGIST