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RESEARCH**

*APPLICATION NUMBER:*

**NDA 22-249**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

06 FEB 2008

**NDA:** 22-249-BC

**Drug Product Name**

**Proprietary:** Treanda® (proposed)  
**Non-proprietary:** Bendamustine hydrochloride  
**Drug Product Priority Classification:** 1P

**Review Number:** 2

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

Letter	Stamp	Review Request	Assigned to Reviewer
07-JAN-2008	08-JAN-2008	08-JAN-2008	08-JAN-2008

**Submission History (for amendments only)**

Submission Date(s)	Microbiology Review #	Review Date(s)
19-SEP-2007	1	17-DEC-2007
15-NOV-2007	1	17-DEC-2007

**Applicant/Sponsor**

**Name:** Cephalon, Inc.  
**Address:** 41 Moores Road  
Frazer, PA 19355

**Representative:** Carol S. Marchione  
Senior Director & Group Leader  
Regulatory Affairs

**Telephone:** 610-738-6237  
**E-mail:** [cmarchio@cephalon.com](mailto:cmarchio@cephalon.com)

**Name of Reviewer:** Anastasia G. Lolas

**Conclusion:** Recommended for approval

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Amendment to a new drug application
  2. **SUBMISSION PROVIDES FOR:** Responses to microbiology questions identified in Microbiology Review #1
  3. **MANUFACTURING SITE:** Pharmachemie B.V.  
Swensweg 5  
2003 RN Haarlem  
The Netherlands
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - Lyophilized powder in a 20 mL single-use glass vial
    - Intravenous infusion
    - 100 mg
  5. **METHOD(S) OF STERILIZATION:** \_\_\_\_\_
  6. **PHARMACOLOGICAL CATEGORY:** Antineoplastic agent for treatment of patients with chronic lymphocytic lymphoma (CLL)
- B. **SUPPORTING/RELATED DOCUMENTS:**
- Microbiology Review #1 dated 17-DEC-2007
- C. **REMARKS:** This amendment is an electronic submission and is in response to 6 microbiology questions and 2 comments communicated to the applicant on 17-DEC-2007 (see DFS).

file name: N022249R2.doc

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**Executive Summary**

- I. Recommendations**
- A. Recommendation on Approvability** – NDA 22-249 is recommended for approval based on 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. Brief Description of Microbiology Deficiencies** – None
  - C. Assessment of Risk Due to Microbiology Deficiencies** – N/A
- III. Administrative**
- A. Reviewer's Signature** \_\_\_\_\_  
Anastasia G. Lolas
  - B. Endorsement Block**  
Stephen E. Langille, Ph.D.
  - C. CC Block**  
N/A

6 Page(s) Withheld

Trade Secret / Confidential

Draft Labeling

Deliberative Process

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