

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-627

MICROBIOLOGY REVIEW

**Product Quality Microbiology Review
Review for HFD-120**

22 AUGUST 2003

NDA: 21-627

Drug Product Name

Proprietary: N/A

Non-proprietary: memantine hydrochloride oral solution

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 1 May 2003

Receipt Date: 2 May 2003

Consult Date: 30 June 2003

Date Assigned for Review: 23 July 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: Forest Laboratories

Address: 909 Third Ave; New York, NY

Representative: Jehan D. Rowlands, Pharm.D.

Telephone: 201-386-2013

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: Forest Pharmaceuticals, Inc.
Manufacturing Plant One
3721 Laclede Avenue
St Louis, MO 63108
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Oral Solution, 2 and 4 mg/mL
 5. METHOD(S) OF STERILIZATION: N/A
 6. PHARMACOLOGICAL CATEGORY: Alzheimer's Type Dementia
- 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 a non-sterile, preserved, solution.
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – The drug product has appropriate microbial limits specifications and is adequately preserved (methyl- and propylparaben). 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

1 Page(s) Withheld

 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Bryan Riley
8/27/03 02:31:40 PM
MICROBIOLOGIST

Peter Cooney
8/28/03 02:56:00 PM
MICROBIOLOGIST