CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-645

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD 510

28-January-2005

NDA: 20-645
20-645/N-000/BC

Drug Product Name
Proprietary: Ammonul®
Non-proprietary: Sodium Phenylacetate/Sodium Benzoate Injection 10%

Drug Product Classification: Priority (orphan)

Review Number: 1

Subject of this Review

	20-645	20-645/N-000/BC
Submission Date	August 9, 2004	January 20, 2005
Receipt Date	August 9, 2004	January 21, 2005
Consult Date	August 13, 2004	January 25, 2005
Date Assigned for Review	August 14, 2004	January 28, 2005

Submission History (for amendments only)
Date(s) of Previous Submission(s): Not applicable
Date(s) of Previous Micro Review(s): Not applicable

Applicant/Sponsor
Name: Medicis Pharmaceutical Corp.
Address: 8125 N. Hayden Road,
Scottsdale, AZ 85254

Representative: Michelle Wells
Telephone: 602-808-8800

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** New Drug Application (resubmission)

2. **SUBMISSION PROVIDES FOR:** Contract [redacted] of Ammonul® at Chesapeake Biological Laboratories.

3. **MANUFACTURING SITE:** Chesapeake Biological Laboratories
1111 South Paca St.
Baltimore, Maryland

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**

- Concentrated solution
- Intravenous infusion
- 10% sodium phenylacetate and 10% sodium benzoate

5. **METHOD(S) OF STERILIZATION:** [redacted]

6. **PHARMACOLOGICAL CATEGORY:** treatment of hyperammonemia

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** Ammonul® is an orphan drug product. On January 20, 2005, Medicis Pharmaceuticals Corporation submitted an amendment to the original submission. The data provided in that amendment was incorporated into this review.

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Executive Summary

I. Recommendations

A. Recommendation on Approvability -

NDA 20-645 is recommended for approval from the standpoint of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -

Not applicable

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -

The drug product will be manufactured [redacted] at Chesapeake Biological Laboratories.

B. Brief Description of Microbiology Deficiencies -

No deficiencies were identified based upon the information provided.

C. Assessment of Risk Due to Microbiology Deficiencies -

Not applicable

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Stephen E. Langille, Ph.D.
Supervisor/Team Leader

C. CC Block

In DFS

6 Page(s) Withheld

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_____ Draft Labeling

_____ Deliberative Process

*Withheld Track Number: Microbiology-*1

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/s/

Stephen Langille
1/31/05 06:53:11 AM
MICROBIOLOGIST

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