

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**50-794**

**Microbiology Review(s)**

**Product Quality Microbiology Review**  
**Review for HFD-150**  
**23 April 2004**

**NDA: 50-794**

**Drug Product Name**

**Proprietary: Vidaza**

**Non-proprietary: azacitidine for injectable suspension**

**Drug Product Classification: Anti-neoplastic**

**Review Number: 1**

**Subject of this Review**

**Submission Date: 26 December 2003**

**Receipt Date: 27 December 2003**

**Consult Date: 27 January 2004**

**Date Assigned for Review: 15 March 2004**

**Submission History (for amendments only)**

**Date(s) of Previous Submission(s):**

**Date(s) of Previous Micro Review(s):**

**Applicant/Sponsor**

**Name: Pharmion Corporation**

**Address: 2525 28<sup>th</sup> Street, Boulder, CO 80301**

**Representative: Linnea Tanner**

**Telephone: (720)564-9106**

**Name of Reviewer: Paul Stinavage, Ph.D.**

**Conclusion:** The application is recommended for approval on the basis of sterility assurance. However, the data and descriptions specified in “**H. LIST OF MICROBIOLOGY DEFICIENCIES AND COMMENTS**”, below, should be provided post-approval.

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
  2. **SUPPLEMENT PROVIDES FOR:** N/A
  3. **MANUFACTURING SITES:** Ben Venue Laboratories, Inc.  
300 Northfield Road  
Bedford, Ohio 44146
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** The finished dosage form is classified as an injection, powder, lyophilized, for suspension containing a nominal 100 mg of azacitidine and 100 mg of mannitol in a 30-mL vial.
  5. **STERILIZATION METHOD(S):** \_\_\_\_\_
  6. **PHARMACOLOGICAL CATEGORY:** Anti-neoplastic
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF's \_\_\_\_\_  
\_\_\_\_\_ and IND 64251
- C. **REMARKS:** The product is a lyophilized formulation \_\_\_\_\_ l by Ben Venue  
Laboratories \_\_\_\_\_

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## **Executive Summary**

- I. Recommendations**
- A. Recommendation on Approvability** – The application is recommended for approval on the basis of sterility assurance.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – The data and descriptions specified in “**H. LIST OF MICROBIOLOGY DEFICIENCIES AND COMMENTS**” should be provided post-approval.
- II. Summary of Microbiology Assessments**
- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The product is \_\_\_\_\_ and lyophilized.
- B. Brief Description of Microbiology Deficiencies** – Failure to provide \_\_\_\_\_ validation data and descriptions and failure to provide adequate container/closure integrity evaluation.
- C. Assessment of Risk Due to Microbiology Deficiencies** – minimal
- III. Administrative**
- A. Reviewer's Signature** \_\_\_\_\_
- B. Endorsement Block**  
P. Stinavage  
P. Cooney
- C. CC Block**  
cc:  
Original NDA 50-794  
HFD-150/Division File/NDA 50-794

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/s/

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Paul Stinavage  
4/23/04 01:16:08 PM  
MICROBIOLOGIST  
New NDA for lyophilized product.      \_\_\_\_\_  
      \_\_\_\_\_

Peter Cooney  
4/23/04 01:31:07 PM  
MICROBIOLOGIST