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 28th 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.
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
   
   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 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
Redacted 4
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

[Signature]

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