APPLICATION NUMBER:
21-711

MICROBIOLOGY REVIEW(S)
Product Quality Microbiology Review
Review for HFD-160

3 JUNE 2004

NDA: 21-711

Drug Product Name
Proprietary: VASOVIST
Non-proprietary: Gadofosveset Trisodium
Drug Product Priority Classification: S

Review Number: 1

Subject of this Review
Submission Date: 12 December 2003
Receipt Date: 15 December 2003
Consult Date: 24 December 2003
Date Assigned for Review: 12 January 2004

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: EPIX Medical
Address: 71 Rogers Street; Cambridge, MA 02142
Representative: Robert Morgan, Esq.
Telephone: 617-250-6050

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommend for Approval
Product Quality Microbiology Data Sheet

A.  1. TYPE OF SUPPLEMENT: N/A
    2. SUPPLEMENT PROVIDES FOR: N/A
    3. MANUFACTURING SITE: Mallinckrodt Medical Inc
       8800 Durant Rd
       Raleigh, NC 27616

    4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
       STRENGTH/POTENCY: Sterile liquid for IV administration, 0.25
       mmol/mL

    5. METHOD(S) OF STERILIZATION: Terminal Moist Heat

    6. PHARMACOLOGICAL CATEGORY: Magnetic Resonance
       Angiography

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: N/A

date: 21711.doc
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 terminally sterilized using moist heat.

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

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
5 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)
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/s/

Bryan Riley
6/30/04 10:11:50 AM
MICROBIOLOGIST

Peter Cooney
6/30/04 11:13:11 AM
MICROBIOLOGIST