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RESEARCH**

APPLICATION NUMBER:

22-325

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

19 NOVEMBER 2008

NDA: 22-325

Drug Product Name

Proprietary: NEXTERONE IV

Non-proprietary: amiodarone hydrochloride

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
2/21/2008	2/25/2008	4/17/2008	4/24/2008

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Prism Pharmaceuticals Inc.

Address: 1150 First Avenue, Suite 1050, King of Prussia, PA 19406

Representative: Daniel Cushing

Telephone: 610-994-0092

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

Conclusion: Approvable pending resolution of a product quality microbiology deficiency (Please see "LIST OF MICROBIOLOGY DEFICIENCIES" on page 10).

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original New Drug Application
 2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product
 3. **MANUFACTURING SITES:**

 Vials: HollisterStier Laboratories
 3525 North Regal Street
 Spokane, WA 99207

 Syringes: Baxter Pharmaceutical Solutions
 927 S. Curry Pike
 Bloomington, IN 47403
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile aqueous solution unit-dose in a pre-filled syringe or glass vial for intravenous administration, 50 mg/mL (3 mL/5 mL syringe and 3 mL/5 mL vial, 9 mL/10 mL vial or 18 mL/20 mL vial).
 5. **METHOD(S) OF STERILIZATION** _____ **b(4)**
 6. **PHARMACOLOGICAL CATEGORY:** treatment of ventricular tachycardia and ventricular fibrillation
- B. **SUPPORTING/RELATED DOCUMENTS:** Product Quality Microbiology Reviews of DMF 4030 (reviews dated 28 August 2007 and 26 February 2007), DMF 10304 (review dated 14 October 2008) and DMF _____ (review dated 9 July 2008). **b(4)**
- C. **REMARKS:** This was an electronic submission in the eCTD format. An initial quality assessment (IQA) was performed by ONDQA (dated 24 March 2008).

filename: N022325R1.doc

Executive Summary

I. Recommendations

A. **Recommendation on Approvability** – This submission is approvable, pending resolution of a product quality microbiology deficiency (Please see “LIST OF MICROBIOLOGY DEFICIENCIES” on page 10).

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 _____ **b(4)**

B. **Brief Description of Microbiology Deficiencies** – The endotoxin specification is too high for the proposed maximum dose.

C. **Assessment of Risk Due to Microbiology Deficiencies** – The endotoxin specification could result in the patient being exposed to potentially harmful amounts of endotoxin.

III. Administrative

A. **Reviewer's Signature** _____
Bryan S. Riley, Ph.D.

B. **Endorsement Block** _____
James L. McVey
Microbiology Team Leader

C. **CC Block**
N/A

7 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

**This is a representation of an electronic record that was signed electronically and
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/s/

Bryan Riley
11/20/2008 09:06:43 AM
MICROBIOLOGIST

James McVey
11/20/2008 10:12:13 AM
MICROBIOLOGIST
I concur.