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RESEARCH**

APPLICATION NUMBER:

205579Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

11 June 2014

NDA: 205-579/N000

Drug Product Name

Proprietary: Ryanodex Suspension for Injection

Non-proprietary: dantrolene sodium

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
21 January 2014	22 January 2014	28 January 2014	30 January 2014
28 May 2014	28 May 2014	NA	NA

Submission History (for 2nd Reviews or higher)

Applicant/Sponsor

Name: Eagle Pharmaceutical, Inc.

Address: 5 Tice Boulevard
Suite 315
Woodcliff Lake, New Jersey 07677

Representative: Foma Rashkovsky
Senior Director, Regulatory Affairs

Telephone: (201) 326-5309

Name of Reviewer: Denise A. Miller

Conclusion: Recommended for approval from a quality microbiology perspective.

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original Application
 2. **SUBMISSION PROVIDES FOR:** Original Marketing application
 3. **MANUFACTURING SITE:**
[REDACTED] (b) (4)
[REDACTED]
[REDACTED] (b) (4)
[REDACTED]
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Dosage Form: Sterile Lyophilized Powder for Reconstitution
 - Route of Administration: Intravenous
 - Strength/Potency: 250 mg/vial in a 20 mL vial.
 5. **METHOD(S) OF STERILIZATION:** [REDACTED] (b) (4)
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of malignant hyperthermia

B. **SUPPORTING/RELATED DOCUMENTS:**

DMF [REDACTED] (b) (4) **Type V** [REDACTED] (b) (4)

Letter of authorization was dated 24 December 2013. NDMS review completed on 8 May 2014 determined the DMF was adequate in support of the [REDACTED] (b) (4) for this application.

DMF [REDACTED] (b) (4) **Type V** [REDACTED] (b) (4)

The Letter of Authorization was dated 27 April 2012 referenced Annual Update 8 (September 09, 2011 submission) for the [REDACTED] (b) (4)

This submission was reviewed by OGD on 12-13-2011 and found to be adequate. Annual update 9 has since been submitted to the DMF. This update was reviewed by OGD on 08-07-2013 and was adequate. The DMF supports the use of the [REDACTED] (b) (4) for this application.

C. REMARKS:

This is an orphan drug (Orphan Designation: 03-1797)

An information request was sent regarding the [REDACTED] (b) (4) [REDACTED] for the drug product on 15 May 2014. A response was submitted on 28 May 2014. A review of the response is found in section P.3.5 on page 8 of this review.

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** - Recommended for approval from a quality microbiology perspective.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** - NA

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – [REDACTED] ^{(b) (4)}
- B. **Brief Description of Microbiology Deficiencies** – There were no deficiencies identified in the information provided.
- C. **Assessment of Risk Due to Microbiology Deficiencies** – NA
- D. **Contains Potential Precedent Decision(s)**- Yes No

III. Administrative

- A. **Reviewer's Signature** _____
Denise A. Miller
Microbiologist, OPS/NDMS
- B. **Endorsement Block** _____
Neal J. Sweeney, Ph.D.
Senior Microbiologist, OPS/NDMS
- C. **CC Block**
N/A

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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/

DENISE A MILLER
06/19/2014

NEAL J SWEENEY
06/19/2014