CENTER FOR DRUG EVALUATION AND 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

<table>
<thead>
<tr>
<th>Submit</th>
<th>Received</th>
<th>Review Request</th>
<th>Assigned to Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 May 2014</td>
<td>28 May 2014</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

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:

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:

6. PHARMACOLOGICAL CATEGORY: Treatment of malignant hyperthermia

B. SUPPORTING/RELATED DOCUMENTS:

DMF Type V

Letter of authorization was dated 24 December 2013. NDMS review completed on 8 May 2014 determined the DMF was adequate in support of the for this application.

DMF Type V

The Letter of Authorization was dated 27 April 2012 referenced Annual Update 8 (September 09, 2011 submission) for the 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 for this application.
C. REMARKS:
This is an orphan drug (Orphan Designation: 03-1797)
An information request was sent regarding the [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.

filename: N205579N000R1.docx
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 -

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