CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205388Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

Product Quality Microbiology Review

11/22/2013

NDA: 205388

Drug Product Name
Proprietary: Omidria
Non-proprietary: OMS302, phenylephrine HCl and Ketorolac tromethamine

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
7/30/2013	7/30/2013	7/30/2013	7/31/2013
11/22/2013	11/22/2013	N/A	N/A

Submission History (for 2nd Reviews or higher)
None

Applicant/Sponsor
Name: Omeros Corporation
Address: 201 Elliott Avenue West, Seattle, WA 28119
Representative: Catherine Melfi
Telephone: 206 676-5000

Name of Reviewer: Steven P. Donald, M.S.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: Original NDA

2. SUBMISSION PROVIDES FOR: Manufacture and marketing of a sterile drug product.

3. MANUFACTURING SITE: [redacted]

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Injection, Solution, Concentrate for irrigation, intraocular administration; 12.4 mg/mL PE and 4.24 mg/mL KE in a 5 mL [redacted] glass vial.

5. METHOD(S) OF STERILIZATION: [redacted]

6. PHARMACOLOGICAL CATEGORY: combination drug product: NSAID/analgesic.

B. SUPPORTING/RELATED DOCUMENTS:

- DMF [redacted], LOA date 2/21/13, [redacted] and associated microbiology review D[redacted]_2011May20_A1.doc, dated 10/15/2013.
- DMF [redacted], LOA date 3/11/2013, [redacted], for stopper endotoxin reduction, submission date 1/24/2013, and associated Generic Drugs microbiology review [redacted]mic24.doc, dated 2/25/2013.

C. REMARKS: An information request was sent to the sponsor on 10/16/13 requesting an LOA for the stopper BER process and for identification of holding periods. This information was satisfactorily provided on 10/24/13. An information request also was provided to the sponsor in the 74 day letter (9/18/2013) that requested information on the storage period for the reconstituted and diluted product. An email from the sponsor was sent to the project manager on 9/24/13 indicating compliance with the recommendation that the post dilution storage period be not more than 4 hours at room temperature or 24 hours under refrigerated conditions. The sponsor indicated that information on the storage period is included in section 3.2.P.2.6 of the eCTD. Review of this section of the eCTD reveals that only chemical stability and compatibility issues are addressed. Clarification was requested on 11/15/2013 through an email to the sponsor from the PM. The applicant provided an official response on 11/22/2013 which is reviewed herein.

filename: N205388r1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability - Recommended for Approval

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 –
No product quality microbiology deficiencies were identified based upon the information provided.

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

D. Contains Potential Precedent Decision(s)- ☐ Yes ☒ No

III. Administrative

A. Reviewer's Signature _____
Steven P. Donald, M.S.
Microbiology Reviewer

B. Endorsement Block_____
Stephen Langille, Ph.D.
Senior Microbiology Reviewer

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/

STEVEN P DONALD
12/16/2013

STEPHEN E LANGILLE
12/16/2013