CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202515Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

23 SEPTEMBER 2011

NDA: 202-515

Drug Product Name
Proprietary: N/A
Non-proprietary: Morphine Sulfate Injection, USP

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
14 January 2011	14 January 2011	28 January 2011	1 February 2011

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Hospira Inc.
Address: 275 North Field Dr., Dept. 0389, Bldg. H2-2, Lake Forest, IL 60045
Representative: Melissa A. Nguyen
Telephone: 620-241-6200, ext 6315

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

Conclusion: Approvable pending resolution of product quality microbiology labeling issue (see "List of Microbiology Deficiencies" at the end of this review).

Product Quality Microbiology Data Sheet

A. 1. TYPE OF SUBMISSION: 505(b)(2) NDA

2. SUBMISSION PROVIDES FOR: A sterile parenteral drug product

3. MANUFACTURING SITES:
Hospira, Inc.
1776 N. Centennial Dr.
McPherson, KS 67460

Hospira, Inc.
HWY 301 North
Rocky Mount, NC 27801

4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile aqueous solution in a variety of container closures (see 3.2.P.1 Description of the Drug Product) for i.v (b) (4) injection, 2, 4, 8, 10, 15, (b) (4) mg/mL.

5. METHOD(S) OF STERILIZATION: (b) (4) Fill

6. PHARMACOLOGICAL CATEGORY: Opioid Analgesic

B. SUPPORTING/RELATED DOCUMENTS: N/A

C. REMARKS: This was an eCTD submission. This NDA was submitted in response to the agency's position that all marketed drug products must have an approved application.

filename: N202515R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is approvable pending resolution of product quality microbiology deficiencies (see "List of Microbiology Deficiencies" at the end of this review).

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) filled.

B. Brief Description of Microbiology Deficiencies – The proposed (b) (4) are not supported by microbiological data.

C. Assessment of Risk Due to Microbiology Deficiencies – (b) (4)

III. Administrative

A. Reviewer's Signature _____

Bryan S. Riley, Ph.D.
Senior Review Microbiologist, OPS/NDMS

B. Endorsement Block _____

Stephen E. Langille, Ph.D.
Senior Review 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/

BRYAN S RILEY
09/28/2011

STEPHEN E LANGILLE
09/29/2011