# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

**22-160**

# MICROBIOLOGY REVIEW(S)

# Product Quality Microbiology Review

**30 NOVEMBER 2007**

**NDA:** 22-160 BI

**Drug Product Name**
**Proprietary:** N/A
**Non-proprietary:** Oxaliplatin Injection
**Drug Product Priority Classification:** S

**Review Number:** 2

**Dates of Submission(s) Covered by this Review**

| Letter | Stamp | Review Request | Assigned to Reviewer |
|---|---|---|---|
| 11/7/2007 | 2/9/2007 | N/A | 11/20/2007 |

**Submission History (for amendments only):** N/A

| Submission Date(s) | Microbiology Review # | Review Date(s) |
|---|---|---|
| 2/9/2007 | 1 | 11/7/2007 |

**Applicant/Sponsor**
**Name:** SICOR Pharmaceuticals
**Address:** 19 Hughes, Irvine, CA 92618-1902
**Representative:** Rosalie Lowe
**Telephone:** 949-457-2808

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

**Conclusion:** Recommended for Approval

# Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Amendment to Original NDA

2. **SUBMISSION PROVIDES FOR:** Response to a Product Quality Microbiology Deficiency

3. **MANUFACTURING SITE:** Pharmachemie B.V.
Swensweg 5
NL-2031 GA Haarlem
The Netherlands

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** A sterile aqueous solution in a glass vial for parenteral administration, 50 mg/10 mL and 100 mg/20 mL

5. **METHOD(S) OF STERILIZATION** (b) (4)

6. **PHARMACOLOGICAL CATEGORY:** Treatment of colorectal cancer

B. **SUPPORTING/RELATED DOCUMENTS:** Product Quality Microbiology review of DMF (b) (4) (dated 30 November 2007).

C. **REMARKS:** A product quality microbiology information request was sent to the applicant via Fax on 10 September 2007. This amendment was submitted in response to that information request.

**filename:** N022160R1.doc

# Executive Summary

## I. Recommendations

**A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.

**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 s (b) (4) (b) (4)

**B. Brief Description of Microbiology Deficiencies** – N/A

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

## 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

## Product Quality Microbiology Assessment

The following information request was Faxed to the applicant on 10 September 2007.

(b) (4)

[redacted]

**ADEQUATE**

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/s/

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Bryan Riley
12/3/2007 11:13:29 AM
MICROBIOLOGIST

James McVey
12/4/2007 02:28:54 PM
MICROBIOLOGIST
I concur with this reviewer's conclusions.

# Product Quality Microbiology Review

**7 NOVEMBER 2007**

**NDA:** 22-160

**Drug Product Name**
**Proprietary:** N/A
**Non-proprietary:** Oxaliplatin Injection
**Drug Product Priority Classification:** S

**Review Number:** 1

**Dates of Submission(s) Covered by this Review**

| Letter | Stamp | Review Request | Assigned to Reviewer |
|---|---|---|---|
| 2/9/2007 | 2/9/2007 | 3/1/2007 | 5/30/2007 |

**Submission History (for amendments only):** N/A

**Applicant/Sponsor**
**Name:** SICOR Pharmaceuticals
**Address:** 19 Hughes, Irvine, CA 92618-1902
**Representative:** Rosalie Lowe
**Telephone:** 949-457-2808

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

**Conclusion:** Approvable pending resolution of product quality microbiology deficiency. Please see "LIST OF MICROBIOLOGY DEFICIENCIES" on page 11 of this review.

# Product Quality Microbiology Data Sheet

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

2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product

3. **MANUFACTURING SITE:** Pharmachemie B.V.
Swensweg 5
NL-2031 GA Haarlem
The Netherlands

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** A sterile aqueous solution in a glass vial for parenteral administration, 50 mg/10 mL and 100 mg/20 mL

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

6. **PHARMACOLOGICAL CATEGORY:** Treatment of colorectal cancer

B. **SUPPORTING/RELATED DOCUMENTS:** N/A

C. **REMARKS:** This application was submitted electronically in the CTD format (not eCTD). A product quality microbiology information request was sent to the applicant via Fax on 10 September 2007.

**filename:** N022160R1.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 11 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)

**B. Brief Description of Microbiology Deficiencies** – (b) (4)

**C. Assessment of Risk Due to Microbiology Deficiencies** – The suitability of the (b) (4) process cannot be determined without assessing the sterilization process validation for all of the sterile materials used in the manufacturing process.

## 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

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/s/
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Bryan Riley
11/8/2007 08:02:17 AM
MICROBIOLOGIST

It's back.

James McVey
11/8/2007 08:13:06 AM
MICROBIOLOGIST
I concur with the conclusions drawn by the primary reviewer.