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RESEARCH**

APPLICATION NUMBER:
50-809

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

23-May-2006

NDA: 50-809

Drug Product Name

Proprietary: Azithromycin

Non-proprietary: Azithromycin for Injection

Drug Product Priority Classification: Standard

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
7/29/05	8/2/05	8/8/05	8/29/05
5/10/06	5/11/06	N/A	N/A
5/17/06	5/18/06	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Sicor Pharmaceuticals Inc.

Address: 19 Hughes
Irvine California

Representative: Not provided

Telephone: 949-455-4700

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
 2. **SUBMISSION PROVIDES FOR:** Aseptic processing operations
 3. **MANUFACTURING SITE:** Sicor Pharmaceuticals Inc.
19 Hughes
Irvine, CA 92618-1902
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Injection
 - 500 mg/vial or 2.5 g/vial
 5. **METHOD(S) OF STERILIZATION:** Aseptic processing
 6. **PHARMACOLOGICAL CATEGORY:** Antibiotic
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** Product quality microbiology deficiencies were conveyed to the applicant on April 12, 2006 and May 15, 2006. The applicant responded to these deficiencies in documents dated May 10, 2006 and May 17, 2006.

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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability -**
NDA 50-809 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
Azithromycin for injection will be aseptically processed and lyophilized at Sicor's Irvine, California site.
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille, Ph.D.
- B. Endorsement Block** _____
Bryan Riley, Ph.D.
- C. CC Block**
N/A

12 Page(s) Withheld

X § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

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/s/

Stephen Langille
5/30/2006 08:40:19 AM
MICROBIOLOGIST

Bryan Riley
5/30/2006 09:09:08 AM
MICROBIOLOGIST