

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-996

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

22 SEPTEMBER 2006

NDA: 21-996

Drug Product Name

Proprietary:

Non-proprietary: ketotifen fumarate ophthalmic solution 0.025%

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
1/31/2006	2/1/2006	3/10/2006	3/17/2006
8/30/2006	8/30/2006	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Alimera Sciences, Inc.

Address: 6120 Windward Parkway Suite 290, Alpharetta, GA 30005

Representative: Barbara Bauschka

Telephone: 678-527-1330

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

Conclusion: Recommend for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** New Drug Application (505(b)(2))
 2. **SUBMISSION PROVIDES FOR:** A sterile ophthalmic drug product
 3. **MANUFACTURING SITE:** []
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile preserved aqueous solution in 10 mL plastic bottle with dropper tip cap for ophthalmic administration, 0.025%.
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Anti-histamine
- B. **SUPPORTING/RELATED DOCUMENTS:** DMF _____ and NDA amendment (BI) dated 30 August 2006.
- C. **REMARKS:** This is a Rx to OTC switch 505(b)(2) NDA

filename: N021996R1.doc

**APPEARS THIS WAY
ON ORIGINAL**

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 filled.
- 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** _____
Stephen Langille, Ph.D.
- C. CC Block**
N/A

3 Page(s) Withheld

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

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

**This is a representation of an electronic record that was signed electronically and
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/s/

Bryan Riley
9/25/2006 02:32:13 PM
MICROBIOLOGIST

Stephen Langille
9/25/2006 02:50:34 PM
MICROBIOLOGIST