

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-756

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-550

3 DECEMBER 2004

NDA: 21-756 and amendment (10 Nov 2004)

Drug Product Name

Proprietary: Macugen

Non-proprietary: pegaptanib sodium injection

Drug Product Priority Classification: P

Review Number: 1

Subject of this Review

Submission Date: 17 June 2004

Receipt Date: 17 June 2004

Consult Date: 29 June 2004

Date Assigned for Review: 9 July 2004

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Eyetech Pharmaceuticals

Address: Three Times Square, 12th floor New York, NY

Representative: Loni da Silva

Telephone: 212-824-3166

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

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUPPLEMENT:** N/A
 2. **SUPPLEMENT PROVIDES FOR:** N/A
 3. **MANUFACTURING SITE:** /
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Pre-filled 1 mL syringe, 0.3 mg 90 uL, for intra-ocular injection.
 5. **METHOD(S) OF STERILIZATION:** —
 6. **PHARMACOLOGICAL CATEGORY:** Macular degeneration
- B. **SUPPORTING/RELATED DOCUMENTS:** NDA amendment dated 10 November 2004 proposed changes to manufacturing process.
- C. **REMARKS:** This was an electronic submission in the CTD format.

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Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology. Please see “Review of Amendment dated 10 November 2004” on pages 8 and 9.
- 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. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Bryan S. Riley, Ph.D. (Microbiology Reviewer)
Microbiology Supervisor
- C. **CC Block**
N/A

6 Page(s) Withheld

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Bryan Riley
12/3/04 03:23:06 PM
MICROBIOLOGIST

David Hussong
12/3/04 03:41:08 PM
MICROBIOLOGIST