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.

filename: N021756R1.doc
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
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