CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-737

MICROBIOLOGY REVIEW

Product Quality Microbiology Review
Review for HFD-550

18 MARCH 2005

NDA:	21-737
Drug Product Name	
Proprietary:	Retisert™
Non-proprietary:	Fluocinolone Acetonide Intravitreal Implant
Drug Product Classification:	S1
Review Number:	1

Subject of this Review	**Original**	**Amendment**
Submission Date:	October 07, 2004	March 08, 2005
Receipt Date:	October 12, 2004	March 09, 2005
Consult Date:	October 14, 2004	March 11, 2005
Date Assigned for Review:	October 26, 2004	NA

Submission History (for amendments only)
Date(s) of Previous Submission(s): NA
Date(s) of Previous Micro Review(s): NA

Applicant/Sponsor	
Name:	Bausch & Lomb
Address:	Tampa, Florida 33637
Representative:	Yelen Concepcion, Manager, Regulatory Affairs
Telephone:	813-866-2568
Name of Reviewer:	Vinayak B. Pawar
Conclusion:	The application is recommended for approval from microbiological standpoint.

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original NDA (Fast track)

2. **SUPPLEMENT PROVIDES FOR:** NA

3. **MANUFACTURING SITE:** IDA Industrial Estate, Waterford, Ireland

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 0.59mg Intravitreal Implant

5. **METHOD(S) OF STERILIZATION:** ———

6. **PHARMACOLOGICAL CATEGORY:** For the treatment of posterior Uveitis.

B. **SUPPORTING/RELATED DOCUMENTS:** None

C. **REMARKS:** The consult requests review of NDA 21-737 for the Drug product Retisert™ an intravitreal implant for the treatment of posterior uveitis. Fourteen volumes of the application were submitted for review. The sponsor was contacted on March 4, 2005 for clarification of the verification dose criteria and as a result an amendment was submitted on March 8, 2005.

filename: C:\my documents\review\NDA\N021737R1

Executive Summary

I. Recommendations

A. Recommendation on Approvability – Based on the product quality microbiology review, the application is recommended for review.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable - NA

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – Retisert 0.59mg implant is manufactured in a tablet form and each tablet is assembled in a cup of [redacted] silicon [redacted] with [redacted] PVA and tablet/cup assembly is the [redacted] affixed to the suture tabs using silicon adhesive (see Figure 2). The product is packed in a case sealed in a foiled pouch and placed in a carton (see Figures 3 & 4).

B. Brief Description of Microbiology Deficiencies - None

C. Assessment of Risk Due to Microbiology Deficiencies - NA

III. Administrative

A. Reviewer's Signature _____

B. Endorsement Block

Vinayak B. Pawar, Ph.D.
David Hussong, Ph.D., Microbiology Supervisor

C. CC Block

cc:
Original NDA 21-737
HFD- 550/Division File/Raphael Rodriguez

8 Page(s) Withheld

6 § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Microbiology-_____

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

/s/

Vinayak Pawar
3/18/05 04:16:15 PM
MICROBIOLOGIST

Recommended for approval from microbiological standpoint

David Hussong
3/18/05 04:28:08 PM
MICROBIOLOGIST