

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-731

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Review for HFD-580

19 NOVEMBER 2004

NDA: 21-731

Drug Product Name

Proprietary: Eligard 45 mg

Non-proprietary: leuprolide acetate injectable suspension

Drug Product Priority Classification: S

Review Number: 1

Subject of this Review

Submission Date: 13 February 2004

Receipt Date: 18 February 2004

Consult Date: 27 April 2004

Date Assigned for Review: 28 April 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: Atrix Laboratories

Address: 2579 Midpoint Drive, Fort Collins, CO 80525

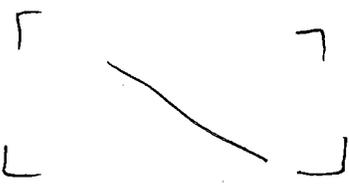
Representative: Cheri Jones

Telephone: 970-212-4901

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 SITES:** Atrix Laboratories
701 Centre Avenue
Fort Collins, CO 80526

 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Lyophilized powder in a Pre-filled syringe for subcutaneous administration, 45 mg
 5. **METHOD(S) OF STERILIZATION:** _____
 6. **PHARMACOLOGICAL CATEGORY:** Treatment of prostate cancer
- B. **SUPPORTING/RELATED DOCUMENTS:** Product quality microbiology reviews of NDA 21-343 dated 11/19/01, 12/13/01 and 12/26/01. NDA 21-731 amendment #003 (17 September 2004)
- C. **REMARKS:** A different strength of the same drug product and delivery system is currently approved for manufacture at _____ The applicant would also like to manufacture this drug product at it's own facility in Fort Collins, CO. This review deals primarily with the manufacturing facility and process at Atrix. The process at _____ is identical to the approved process for the other strengths of the drug product.

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

5 Page(s) Withheld

§ 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
11/24/04 08:39:07 AM
MICROBIOLOGIST

David Hussong
11/24/04 10:09:54 AM
MICROBIOLOGIST
Microbiology recommends APPROVE

