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:** [redacted]

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 [redacted] 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 [redacted] 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

Withheld Track Number: Microbiology- 1 of 1

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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

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Application : NDA 21731/000
Org Code : 580
Priority : 3S

Sponsor: ATRIX
2579 MIDPOINT DR
FORT COLLINS, CO 80525

Stamp Date : 18-FEB-2004
PDUFA Date : 18-DEC-2004
Action Goal :
District Goal: 19-OCT-2004

Brand Name : ELIGARD(LEUPROLIDE ACETATE)45MG INJ SUSP
Estab. Name:
Generic Name: LEUPROLIDE ACETATE
Dosage Form: (INJECTION)
Strength : 45 MG

FDA Contacts:	J. KIM	Project Manager (HFD-580)	301-827-3003
	S. DE	Review Chemist (HFD-580)	301-827-7516
	M. RHEE	Team Leader (HFD-580)	301-827-4237

Overall Recommendation: ACCEPTABLE on 29-NOV-2004by S. FERGUSON(HFD-322) 301-827-9009

Establishment : CFN : 1722158 FEI : 3001237858
ATRIX LABORATORIES INC
2579 MIDPOINT DR
FORT COLLINS, CO 80525