

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**21-343**

**Microbiology Review(s)**

**REVIEW TO HFD-580  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF/HFD-805  
MICROBIOLOGY REVIEW #3 OF NDA**

26 December 2001

- A.
1. NDA: 21-343/BI amendment
  2. TYPE OF SUPPLEMENT: N/A
  3. SUPPLEMENT PROVIDES FOR: N/A
  4. APPLICANT/SPONSOR: Atrix Laboratories  
2579 Midpoint Drive  
Fort Collins, CO 80525-4417
  5. MANUFACTURING SITE:
  6. DRUG PRODUCT NAME:  
Proprietary:  7.5 mg  
Nonproprietary: Leuprolide Acetate for Injectable Suspension  
Drug Priority Classification: S
  7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:  Drug Product in Sterile Syringe w/  
Sterile Syringe containing ATRIGEL® Delivery System; Subcutaneous Injection; 7.5 mg
  8. METHOD(S) OF STERILIZATION:
  9. PHARMACOLOGICAL CATEGORY: GnRH Agonist
- B.
1. DOCUMENT/LETTER DATE: March 22, 2001
  2. RECEIPT DATE: March 23, 2001
  3. CONSULT DATE: May 15, 2001
  4. DATE OF AMENDMENT: December 19, 2001
  5. ASSIGNED FOR REVIEW: N/A
  6. SUPPORTING/RELATED DOCUMENTS: Microbiology reviews of NDA 21-343 dated 19 Nov. 2001 and 13 Dec. 2001.
- C. REMARKS: This amendment contains the applicant's response to a microbiology deficiency in an amendment (BI, 29 November 2001) to the original application.

D. CONCLUSIONS: This submission is recommended for approval on the basis of product quality microbiology.

*/s/* 1-2-02

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Bryan S. Riley, Ph.D.  
Microbiology Reviewer

cc.: Original NDA 21-343  
HFD 580/Division File  
HFD 580/Project Manager  
HFD 580/Chemist  
HFD 805/Consult File  
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.  
R/D initialed by: Peter Cooney, Ph.D.

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commercial

information

**NDA 21-343**  
**Eligard™ (leuprolide acetate for injectable suspension)**  
**ATRIX Laboratories, Inc.**

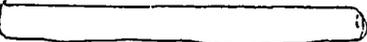
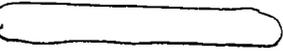
**There was no Micro Efficacy review for this application.**

**APPEARS THIS WAY  
ON ORIGINAL**

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ON ORIGINAL**

**REVIEW TO HFD-580  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF/HFD-805  
MICROBIOLOGY REVIEW #2 OF NDA**

**13 December 2001**

- A.
1. NDA: 21-343 amendment
  2. TYPE OF SUPPLEMENT: N/A
  3. SUPPLEMENT PROVIDES FOR: N/A
  4. APPLICANT/SPONSOR: Atrix Laboratories  
2579 Midpoint Drive  
Fort Collins, CO 80525-4417
  5. MANUFACTURING SITE: 
  6. DRUG PRODUCT NAME:  
Proprietary:  7.5 mg  
Nonproprietary: Leuprolide Acetate for Injectable Suspension  
Drug Priority Classification: S
  7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:  Drug Product in Sterile Syringe w/  
Sterile Syringe containing ATRIGEL® Delivery System; Subcutaneous Injection; 7.5 mg
  8. METHOD(S) OF STERILIZATION: 
  9. PHARMACOLOGICAL CATEGORY: GnRH Agonist
- B.
1. DOCUMENT/LETTER DATE: March 22, 2001
  2. RECEIPT DATE: March 23, 2001
  3. CONSULT DATE: May 15, 2001
  4. DATE OF AMENDMENT: November 29, 2001
  5. ASSIGNED FOR REVIEW: N/A
  6. SUPPORTING/RELATED DOCUMENTS:
- C. REMARKS: This amendment contains the applicant's responses to microbiology deficiencies in the original application.

D. CONCLUSIONS: This submission is approvable pending resolution of microbiology deficiencies. Please see "Microbiologist's List of Deficiencies" at the end of this review.

/S/

12-17-01

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Bryan S. Riley, Ph.D.  
Microbiology Reviewer

cc.: Original NDA 21-343  
HFD 580/Division File  
HFD 580/Project Manager  
HFD 580/Chemist  
HFD 805/Consult File  
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.  
R/D initialed by: Peter Cooney, Ph.D.

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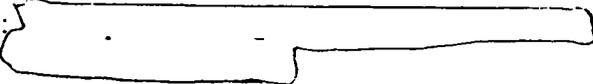
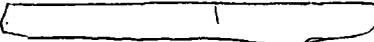
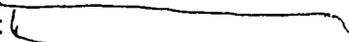
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**REVIEW TO HFD-580  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF/HFD-805  
MICROBIOLOGY REVIEW #1 OF NDA**

**19 November 2001**

- A.
1. NDA: 21-343
  2. TYPE OF SUPPLEMENT: N/A
  3. SUPPLEMENT PROVIDES FOR: N/A
  4. APPLICANT/SPONSOR: Atrix Laboratories  
2579 Midpoint Drive  
Fort Collins, CO 80525-4417
  5. MANUFACTURING SITE: 
  6. DRUG PRODUCT NAME:  
Proprietary:  7.5 mg  
Nonproprietary: Leuprolide Acetate for Injectable Suspension  
Drug Priority Classification: S
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  4. DATE OF AMENDMENT: N/A
  5. ASSIGNED FOR REVIEW: May 22, 2001
  6. SUPPORTING/RELATED DOCUMENTS:
- C. REMARKS:

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- D. **CONCLUSIONS:** This submission is approvable pending resolution of microbiology deficiencies. Please see "Microbiologist's List of Deficiencies" at the end of this review.

11-19-01

/S/

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Bryan S. Riley, Ph.D.  
Microbiology Reviewer

cc.: Original NDA 21-343  
HFD 580/Division File  
HFD 580/Project Manager  
HFD 580/Chemist  
HFD 805/Consult File  
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.  
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