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RESEARCH**

APPLICATION NUMBER:

22-057

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review
Review for Division of Reproductive and Urologic Drug Products

15 February 2007

NDA: 22-057

Drug Product Name

Proprietary: Endometrin® Vaginal Tablet

Non-proprietary: progesterone

Drug Product Priority Classification: S1

Review Number:

Dates of Submission(s) Covered by this Review

Letter	Stamp	Consult Sent	Assigned to Reviewer
August 21, 2006	Electronic Submission	October 3, 2006	October 5, 2006

Submission History (for amendments only)-NA

Applicant/Sponsor

Name: Ferring Pharmaceuticals, Inc.

Address: 400 Rella Boulevard, New York, 10901

Representative: James H. Conover, Executive Director, RA

Telephone: 845-770-2668

Name of Reviewer: Vinayak B. Pawar

Conclusion: The application is recommended for approval on condition that the Microbial Limits test currently conducted at release must in addition be performed at stability end point.

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUBMISSION:** Original NDA
2. **SUBMISSION PROVIDES FOR:** A micronized progesterone compressed into 100 mg tablet to be used as an assisted reproductive technology treatment.
3. **MANUFACTURING SITE:** New York
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Tablet is vaginal inserted to supplement progesterone levels for pregnancy treatment.
5. **METHOD(S) OF STERILIZATION:** — tablet manufacture. **b(4)**
6. **PHARMACOLOGICAL CATEGORY:** Hormonal therapy.
- B. **SUPPORTING/RELATED DOCUMENTS:** None
- C. **REMARKS:** The consult requests review of Original NDA 22-057 for review of Microbiological attributes pertaining to the drug product Endometrin® Vaginal Tablet. The consult was sent to determine if the moisture limit is appropriate for this dosage and microbial limits test should be included on stability. The application was submitted in an electronic CTD format.

filename: N022057R1

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Executive Summary**I. Recommendations**

- A. Recommendation on Approvability** – The application is approved on condition that the Microbial Limits test currently conducted at release must in addition be performed at stability end point.
- 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** – The tablet manufacturing process is described in a flow diagram (see Figure 1).
- B. Brief Description of Microbiology Deficiencies - None**
- C. Assessment of Risk Due to Microbiology Deficiencies - NA**

III. Administrative

- A. Reviewer's Signature** _____
Vinayak Pawar, Ph.D.
- B. Endorsement Block** _____
Bryan Riley, Ph.D.
- C. CC Block**
N/A

4 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Vinayak Pawar
2/28/2007 01:10:11 PM
MICROBIOLOGIST

Recommended for approval on condition that Microbial Limits Test
be performed at release and stability end point.

Bryan Riley
2/28/2007 01:17:36 PM
MICROBIOLOGIST