

Mecier

MAR - 1 1999

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW # 1 OF NDA

February 24, 1999

- A. 1. NDA 20-908
SPONSOR Novo Nordisk Pharmaceuticals

- 2. PRODUCT NAMES: Vagifem®
- 3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Tablet, Vaginal
- 4. METHOD(S) OF STERILIZATION: N/A
- 5. PHARMACOLOGICAL CATEGORY: Estrogen
- 6. DRUG PRIORITY CLASSIFICATION:

- B. 1. DATE OF INITIAL SUBMISSION: N/A
- 2. DATE OF AMENDMENT:
- 3. RELATED DOCUMENTS:
- 4. ASSIGNED FOR REVIEW: February 11, 1999

- C. REMARKS: The drug product is a vaginal, estradiol tablet. The review addresses the microbial limits specifications for this non-sterile product.

D. CONCLUSIONS: This application is approved from the standpoint of product quality microbiology.

/S/

2-24-99

Bryan Riley, Ph.D.

JRC 3/1/99

cc:

HFD 580/Consult File
HFD 580/J. Mercier
HFD 580/Rev Chemist
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 2/24/99
R/D initialed by: P. Cooney,