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RESEARCH**

*APPLICATION NUMBER:*

**21-048**

**MICROBIOLOGY REVIEW**

JUL 20 1999

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

July 20, 1999

A. 1. NDA 21-048

SPONSOR Wyeth-Ayerst  
P.O. Box 8299  
Philadelphia, PA 19101-8299

2. PRODUCT NAMES: 17  $\beta$ -Estradiol Transdermal System

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Transdermal Patch

4. METHOD(S) OF STERILIZATION: na

5. PHARMACOLOGICAL CATEGORY:

6. DRUG PRIORITY CLASSIFICATION:

B. 1. DATE OF INITIAL SUBMISSION: November 20, 1998

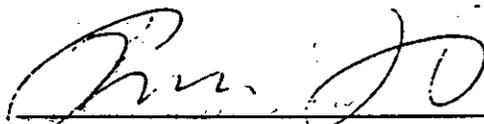
2. DATE OF AMENDMENT:

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: June 7, 1999

C. REMARKS: This review addresses the microbial limit tests and specifications for the drug product.

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

  
Bryan Riley, Ph.D. 7-20-99

PAC 7/20/99

cc:

HFD 580/Consult File  
HFD 580/D. Spell-LeSane  
HFD 580/Rev Chemist  
HFD 805/Consult File  
HFD 805/B. Riley

Drafted by: B. Riley, 7/20/99  
R/D initialed by: P. Cooney,

1   Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling