

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-791

MICROBIOLOGY REVIEW(S)

OCT 14 1997

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2
14 October 1997

A. 1. NDA 20-791

APPLICANT: Alza Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

2. PRODUCT NAMES: Testoderm® AT (testosterone transdermal system)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Patch for intended for daily application to intact skin.
4. METHODS OF STERILIZATION:
The drug product is a nonsterile dosage form.
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for use as topical hormonal replacement therapy.

B. 1. DATE OF INITIAL SUBMISSION: 19 December 1996

2. DATE OF AMENDMENT: 28 August 1997
3. RELATED DOCUMENTS: (none)
4. ASSIGNED FOR REVIEW: 16 September 1997

C. REMARKS:

The product is a patch for topical application. The applicant states in the application cover letter that the product contains no preservative and microbial limits have not been established. Testing of the product has indicated that it demonstrates bactericidal properties. Therefore, the applicant feels that microbial limits are not warranted.

Alza Corporation, NDA 20-791; Testoderm® AT, Microbiologist's Review #2

D. CONCLUSIONS: The application is recommended for approval based on the information provided.

14 October 1997
Paul Stinavage, Ph.D.

cc: Original NDA 20-791
HFD-580/T. Rumble/A. Mitra/Div. Files
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 14 October 1997
R/D initialed by P. Cooney

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1
24 July 1997

A. 1. NDA 20-791

APPLICANT: Alza Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

2. PRODUCT NAMES: Testoderm® AT (testosterone transdermal system)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Patch for intended for daily application to intact skin.
4. METHODS OF STERILIZATION:
The drug product is a nonsterile dosage form.
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated for use as topical hormonal replacement therapy.

B. 1. DATE OF INITIAL SUBMISSION: 19 December 1996

2. DATE OF AMENDMENT: (none)
3. RELATED DOCUMENTS: (none)
4. ASSIGNED FOR REVIEW: 3 June 1997

C. REMARKS: The product is a patch for topical application. The applicant states in the application cover letter that the product contains no preservative and microbial limits have not been established. Testing of the product has indicated that it demonstrates bactericidal properties. Therefore, the applicant feels that microbial limits are not warranted.

Alza Corporation, NDA 20-791; Testoderm® AT, Microbiologist's Review #1

D. CONCLUSIONS: The application is approvable pending resolution of microbiology concerns. Specific comments are provided

24 July 1997

Paul Stinavage, Ph.D.
Rtc 7/24/97

cc: Original NDA 20-791
HFD-580/T. Rumble/Div. Files
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 24 July 1997
R/D initialed by P. Cooney