

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-289

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #3 OF NDA 21-289
23 May 2001

- A. 1. NDA 21-289 BC
APPLICANT: Ferring Pharmaceuticals
120 White Plains Road, Suite 400
Tarrytown, NY 10591
2. PRODUCT NAME: Ovanex™ (urofollitropin for injection)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is intended for subcutaneous or intramuscular administration.
4. METHODS OF STERILIZATION:
The drug product is aseptically filled.
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE
INDICATION:
The drug product is used for induction of ovulation and pregnancy in
anovulatory, infertile women. It may also be indicated for the stimulation
of the development of multiple follicles in ovulatory women participating
in an *in vitro* fertilization program.
- B. 1. DATE OF INITIAL SUBMISSION: 28 September 2000
2. DATE OF AMENDMENT: 15 May 2001 (Subject of this
Review)
3. RELATED DOCUMENTS: I _____
_____, NDA 21-047
4. ASSIGNED FOR REVIEW: 23 May 2001
- C. REMARKS: The application is a new NDA submission. The product is to be
manufactured at:
- SP Pharmaceuticals
4272 Balloon Park Road, N.E.
Albuquerque, NM 87019

The product is a lyophilized powder formulated to provide 75 IU of
the active drug.

- D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

Paul Stinavage, Ph.D.

cc: Original NDA 21-289
HFD-805/Stinavage/Consult File
HFD-580/Div File/Spell-LeSane/Lin/Rhee/Bennett/Slaughter/ Olmstead/T.
Rumble

Drafted by: P. Stinavage, 23 May 2001
R/D initialed by P. Cooney

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/s/

Paul Stinavage
5/23/01 08:30:54 AM
MICROBIOLOGIST
Endotoxin specification for finished product.

Peter Cooney
5/23/01 03:37:40 PM
MICROBIOLOGIST

**APPEARS THIS WAY
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Ferring Pharmaceuticals, NDA 21-289, Ovanex™, Microbiologist's Rev. #2 of NDA

- D. CONCLUSIONS: The application is approvable upon resolution of microbiology concerns. Specific comments are provided in "E. Review Notes" and "List of Microbiology Deficiencies".

Paul Stinavage, Ph.D.

cc: Original NDA 21-289
HFD-805/Stinavage/Consult File
HFD-580/Div File/E. DeGuia/T. Rumble

Drafted by: P. Stinavage, 28 March 2001
R/D initialed by P. Cooney

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/s/

Paul Stinavage
4/24/01 04:51:57 AM
MICROBIOLOGIST
Amendment review.

Peter Cooney
4/24/01 10:33:49 AM
MICROBIOLOGIST

APPEARS THIS WAY
ON ORIGINAL

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 21-289
9 January 2001

- A. 1. NDA 21-289
APPLICANT: Ferring Pharmaceuticals
120 White Plains Road, Suite 400
Tarrytown, NY 10591
2. PRODUCT NAME: Ovanex (urofollitropin for injection)
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- B. 1. DATE OF INITIAL SUBMISSION: 28 September 2000
2. DATE OF AMENDMENT: (none)
3. RELATED DOCUMENTS: —
—, NDA 21-047
4. ASSIGNED FOR REVIEW: 23 October 2000
- C. REMARKS: The application is a new NDA submission. The product is to be manufactured at:

SP Pharmaceuticals
4272 Balloon Park Road, N.E.
Albuquerque, NM 87019

The product is a lyophilized powder formulated to provide 75 IU of the active drug.

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Paul Stinavage, Ph.D.

cc: Original NDA 21-289
HFD-805/Stinavage/Consult File
HFD-580/Div File/E. DeGuia/T. Rumble/M. Rhee

Drafted by: P. Stinavage, 9 January 2001
R/D initialed by P. Cooney

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