

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
21-288**

Microbiology Review(s)

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
ADDENDUM TO MICROBIOLOGIST'S REVIEW #2 OF NDA

June 28, 2001

- A. 1. NDA 21-288/BI
21-288/BZ
- U.S. AGENT Target Research Associates
1801 East Second Street
Scotch Plains, NJ 07076
- APPLICANT Debio Recherche Pharmaceutique SA
Route du Levant 146
CH-1920 Martigny
Switzerland
2. PRODUCT NAMES: Trelstar® LA, 11.25 mg (triptorelin pamoate for injectable suspension)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: The product is a lyophilized powder in a 6 cc vial with a rubber stopper. The depot powder consists of 11.25 mg of sterile triptorelin pamoate. The powder is reconstituted with 2 mL Sterile Water for Injection from a prefilled syringe. The syringe is part of the "Debioclip" single dose delivery system that is "blister packed" and sterilized. Microgranules of the active ingredient are suspended in the diluent, and are injected intramuscularly, every 84 days (3 months).
The product is intended for two presentations (volume 2, page 127): the Trelstar LA vial alone, and the Trelstar LA vial in the Debioclip.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Hormone agonist for the palliative treatment of prostate cancer
6. DRUG PRIORITY CLASSIFICATION: 3S
- B. 1. DATE OF INITIAL SUBMISSION: June 29, 2000 (the subject of Microbiologist's Review #1)

2. DATE OF AMENDMENTS: February 5, 2001 (BI), March 5, 2001 (BZ), and May 14, 2001 (BI)
 3. RELATED DOCUMENTS: Memorandum of telephone conversation date February 15, 2001, and Microbiologist's Review #2, dated May 21, 2001.
 4. ASSIGNED FOR REVIEW: March 26, 2001 (both amendments)
- C. REMARKS: This addendum corrects an error in Microbiologist's Review #2 and provides resolution to speculation that resulted in a recommendation for additional studies discussed in a telephone conversation on February 15, 2001.
- D. CONCLUSIONS: The submission is recommended for APPROVAL.

/S/ . . . 6/28/01

David Hussong, Ph.D.

cc:

Original NDA 21-288
HFD 160/Consult File
HFD 580/Division File
HFD 580/CSO/J. Best
HFD 580/Chemist/ D. Lin
HFD 805/D. Hussong

Drafted by: D. Hussong, 06/28/2001

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

May 21, 2001

- A. 1. NDA 21-288/BI
21-288/BZ
- U.S. AGENT Target Research Associates
1801 East Second Street
Scotch Plains, NJ 07076
- APPLICANT Debio Recherche Pharmaceutique SA
Route du Levant 146
CH-1920 Martigny
Switzerland
2. PRODUCT NAMES: Trelstar® LA, 11.25 mg (triptorelin pamoate for injectable suspension)
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The product is intended for two presentations (Volume 2, page 127): the Trelstar LA vial alone, and the Trelstar LA vial in the Debioclip.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Hormone agonist for the palliative treatment of prostate cancer
6. DRUG PRIORITY CLASSIFICATION: 3S
- B. 1. DATE OF INITIAL SUBMISSION: June 29, 2000 (the subject of Microbiologist's Review #1)

2. DATE OF AMENDMENTS: February 5, 2001 (BI), March 5, 2001 (BZ), and May 14, 2001 (BI)
 3. RELATED DOCUMENTS: NDA 20-715 Trelstar® Depot, 3.75 mg (triptorelin pamoate for injectable suspension) was approved previously. The current NDA submission is a new formulation for administration every 3-months.
 4. ASSIGNED FOR REVIEW: March 26, 2001 (both amendments)
- C. REMARKS: The amendments respond to deficiencies that came from Microbiologist's Review #1. The second amendment follows a telephone conversation (February 15, 2001) to discuss strategies for resolving the deficiencies.
- D. CONCLUSIONS: The submission is recommended for APPROVAL.

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6/14/01

David Hussong, Ph.D.

cc:

Original NDA 21-288
HFD 160/Consult File
HFD 580/Division File
HFD 580/CSO/J. Best /K. Colangelo
HFD 580/Chemist/ D. Lin
HFD 805/D. Hussong

Drafted by: D. Hussong, 05/21/2001
R/D initialed by: P. Cooney 6/14/01

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

November 17, 2000

- A. 1. NDA 21-288/N
- U.S. AGENT Target Research Associates
1801 East Second Street
Scotch Plains, NJ 07076
- APPLICANT Debio Recherche Pharmaceutique SA
Route du Levant 146
CH-1920 Martigny
Switzerland
2. PRODUCT NAMES: Trelstar® LA, 11.25 mg (triptorelin pamoate for injectable suspension)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: The product is a lyophilized powder in a 6 cc vial with a rubber stopper. The depot powder consists of 11.25 mg of sterile triptorelin pamoate. The powder is reconstituted with 2 mL Sterile Water for Injection from a prefilled syringe. The syringe is part of the "Debioclip" single dose delivery system that is "blister packed" and sterilized. Microgranules of the active ingredient are suspended in the diluent, and are injected intramuscularly, every 84 days (3 months).
The product is intended for two presentations (volume 2, page 127): the Trelstar LA vial alone, and the Trelstar LA vial in the Debioclip.
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Hormone agonist for the palliative treatment of prostate cancer
6. DRUG PRIORITY CLASSIFICATION: 3S
- B. 1. DATE OF INITIAL SUBMISSION: June 29, 2000
2. DATE OF AMENDMENT: none

3. RELATED DOCUMENTS: NDA 20-715 Trelstar® Depot, 3.75 mg (triptorelin pamoate for injectable suspension) was approved previously. The current NDA submission is a new formulation for administration every 3-months.
 4. ASSIGNED FOR REVIEW: July 19, 2000
- C. REMARKS: The one-month formulation of the product was Trelstar Depot, 3.75 mg. The document for consultative review is volume, containing "Item 4," the CMC section.
- D. CONCLUSIONS: The submission is APPROVABLE. A list of deficiencies follows section "E. Review Notes."

/s/

David Hussong, Ph.D.

cc:

Original NDA 21-288
HFD 160/Consult File
HFD 580/Division File
HFD 580/CSO/J. Best /K. Colangelo
HFD 580/Chemist/ D. Lin
HFD 805/D. Hussong

Drafted by: D. Hussong, 11/17/2000
R/D initialed by: P. Cooney

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NDA 21-288

Trelstar® LA 11.25 mg (triptorelin pamoate for injectable suspension)

Debio Recherche Pharmaceutique S.A.

- The methods validation have not been completed at this time.

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