

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-149**

**MICROBIOLOGY REVIEW**

AUG 25 2000

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

August 23, 2000

- A. 1. NDA: 21-149
2. APPLICANT: Serono Laboratories  
100 Longwater Circle  
Norwell, MA 02061
3. PRODUCT NAME: OVIDREL® (Choriogandotropin alpha) 250 µg : \_\_\_\_\_
4. MANUFACTURER: Serono Pharma, S.p.A.  
Zona Industriale di Modugno  
I-70123 Bari  
Italy

MANUFACTURERS OF RECONSTITUTING SOLUTION:

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(withdrawn August 2, 2000)

5. DOSAGE FORM AND ROUTE OF ADMINISTRATION: This sterile product is lyophilized and contained in \_\_\_\_\_ glass vials with a \_\_\_\_\_ rubber closure. After reconstitution with 1mL Sterile Water for Injection, USP (supplied in a \_\_\_\_\_ glass vial), the product is injected subcutaneously. Three presentations are described:

NDC: \_\_\_\_\_

NDC: \_\_\_\_\_

NDC: \_\_\_\_\_

6. METHODS OF STERILIZATION: The container with active drug product is

7. NAME AND ADDRESS OF MANUFACTURER:

8. PHARMACOLOGICAL CATEGORY: Hormone (recombinant) to enhance fertility

B. 1. DOCUMENT DATE: November 23, 1999

2. DATE ASSIGNED FOR REVIEW: December 20, 1999

3. AMENDMENTS AND OTHERS: June 16, 2000 (amendment in response to May 31, 2000 information request) and August 3, 2000

4. RELATED DOCUMENTS: none

C. REMARKS: The drug product is packaged with a diluent (solvent), Sterile Water for Injection, USP, in 1 mL vials. The "diluent" is manufactured by \_\_\_\_\_ has provided manufacturing and sterility assurance information in their NDA amendment dated June 16, 2000. The inclusion of this information has eliminated the need to refer to \_\_\_\_\_ (not reviewed).

An additional presentation for the diluent was described on page 359 (vol. 11). This presentation is packaged in 1 mL glass ampoules, and is manufactured by \_\_\_\_\_. That product was withdrawn from the NDA in an amendment dated August 3, 2000.

Volume 11 of the original submission contains the end of the CMC information for the 250 µg product, CMC microbiology (Section G), CMC for the \_\_\_\_\_ product and summaries of the \_\_\_\_\_ for reconstituting the product. An amendment (June 16, 2000) provides details of the manufacture of \_\_\_\_\_ in vials by \_\_\_\_\_

D. CONCLUSIONS AND RECOMMENDATIONS: The submission is recommended for APPROVAL from the perspective of microbiology. Specific comments are provided at the end of the review ("List of Microbiology Deficiencies and Comments").

/S/  
David Hussong, Ph.D.

8-23-2000

/S/ 8/25/00

cc:

Original NDA 21-149  
HFD 580/Division File  
HFD 160/Consult File  
HFD 580/CSO/E. DeGuia  
HFD 580/Chemist/D. Wu/ Y. Yang  
HFD 805/D. Hussong

Drafted by: D. Hussong, 08/23/2000  
R/D initialed by: P. Cooney

Filename, d:\nda\s\21-149r1.DOC

NDA 21-149

Ovidrel® (choriogonadotropin alfa for injection)

Serono Laboratories

**Microbiology (efficacy) Reviews and Memo**

**This is not applicable to this NDA.**