

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 21057**

**MICROBIOLOGY REVIEW(S)**

**REVIEW FOR HFD-580  
OFFICE OF NEW DRUG CHEMISTRY  
MICROBIOLOGY STAFF HFD-805**

**Microbiologist's Review #1 of NDA 21-057  
May 20, 1999**

1. **APPLICATION NUMBER:** 21-057  
  
**APPLICANT:** Organon Inc.  
375 Mt. Pleasant Avenue  
West Orange  
New Jersey 07052
  
  2. **PRODUCT NAMES:** Org 37462 (ganirelix acetate) injection
  
  3. **DOSAGE FORM AND ROUTE OF ADMINISTRATION:** Pre-filled 1 ml syringe (250 ug/0.5 ml) for subcutaneous injection.
  
  4. **METHOD(S) OF STERILIZATION:** ✓  
✓
  
  5. **PHARMACOLOGICAL CATEGORY:** 1P; indicated for the prevention of premature LH surges in women undergoing ovarian hyperstimulation.
- B. 1. **DATE OF INITIAL SUBMISSION:** January 28, 1999
2. **AMENDMENT:**
  3. **RELATED DOCUMENTS:**
  4. **ASSIGNED FOR REVIEW:** May 6, 1999
  5. **DATE OF CONSULT REQUEST:** May 6, 1999
- C. **REMARKS:**

Org 37462 (ganirelix acetate) is a gonadotropin releasing hormone (GnRH) antagonist which induces suppression of the pituitary-gonadal axis, with reduced histamine releasing properties. The drug is indicated for the prevention of luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation.

**D. CONCLUSIONS:**

The submission is recommended for approval on issues concerning sterility assurance and microbiology.

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*5/21/99*

**Brenda Uratani, Ph.D.  
Review Microbiologist**

*TAC*

*5/21/99*

cc:

**NDA 21-057  
HFD-580/ Div. File  
HFD-805/ Uratani  
HFD-580/Moore  
drafted by: Brenda Uratani, 5/21/99  
R/D initialed by P. Cooney, 5/21/99**