

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-684

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

Review for HFD-580

13 NOVEMBER 2003

NDA: 21-684

Drug Product Name

Proprietary: Gonal-f

Non-proprietary: follitropin alfa injection

Drug Product Priority Classification: P

Review Number: 1

Subject of this Review

Submission Date: 28 July 2003

Receipt Date: 29 July 2003

Consult Date: 8 August 2003

Date Assigned for Review: 12 August 2003

Submission History (for amendments only)

Date(s) of Previous Submission(s): N/A

Date(s) of Previous Micro Review(s): N/A

Applicant/Sponsor

Name: Serono Inc.

Address: One Technology Place, Rockland, MA 02370

Representative: Pamela Williamson Joyce

Telephone: 781-982-9000

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
 2. SUPPLEMENT PROVIDES FOR: N/A
 3. MANUFACTURING SITE: /
 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY: Sterile aqueous solution for subcutaneous injection in a 3mL glass cartridge in a disposable pen device, 300, 450 and 900 IU/cartridge
 5. METHOD(S) OF STERILIZATION: —
 6. PHARMACOLOGICAL CATEGORY: gonadotropin
- B. SUPPORTING/RELATED DOCUMENTS: NDA 20-378 (Gonal-f)
- C. REMARKS: This drug product is a liquid formulation of an existing approved lyophilized drug product (NDA 20-378).

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§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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/s/

Bryan Riley
11/21/03 07:27:16 AM
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