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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-322

Microbiology Review(s)

**REVIEW TO HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF/HFD-805
MICROBIOLOGY REVIEW #1 OF NDA**

30 JANUARY 2002

- A.
1. NDA: 21-322
 2. TYPE OF SUPPLEMENT: N/A
 3. SUPPLEMENT PROVIDES FOR: N/A
 4. APPLICANT/SPONSOR: Serono, Inc.
100 Longwater Circle
Norwell, MA 02061
 5. MANUFACTURING SITES: Aubonne, Switzerland (drug product) and
C 1
 6. DRUG PRODUCT NAME:
Proprietary: Luveris™
Nonproprietary: lutropin alfa for injection
Drug Priority Classification: S
 7. DOSAGE FORM, ROUTE OF ADMINISTRATION AND
STRENGTH/POTENCY: A glass vial containing a lyophilized powder for
subcutaneous administration following reconstitution, 75 IU/vial; a glass
vial containing 1 mL of WFI (diluent)
 8. METHOD(S) OF STERILIZATION: C 1
 9. PHARMACOLOGICAL CATEGORY: luteinizing hormone
- B.
1. DOCUMENT/LETTER DATE: April 30, 2001
 2. RECEIPT DATE: May 1, 2001
 3. CONSULT DATE: May 4, 2001
 4. DATE OF AMENDMENT: January 25, 2001
 5. ASSIGNED FOR REVIEW: May 24, 2001
 6. SUPPORTING/RELATED DOCUMENTS:
- C. REMARKS:

- D. CONCLUSIONS: This submission is recommended for approval on the basis of product quality microbiology.

Bryan S. Riley, Ph.D.
Microbiology Reviewer

cc.: Original NDA 21-322
HFD 580/Division File
HFD 580/Project Manager
HFD 580/Other
HFD 805/Consult File
HFD 805/ B. Riley

Drafted by: Bryan Riley, Ph.D.
R/D initialed by: Peter Cooney, Ph.D.

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6 Page(s) Withheld



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 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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/s/

Bryan Riley
2/11/02 09:52:09 AM
MICROBIOLOGIST

Peter Cooney
2/11/02 10:24:06 AM
MICROBIOLOGIST