

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-211

MICROBIOLOGY REVIEW

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

5 December 2000

A. 1. NDA 21-211/BC

SPONSOR Organon, Inc.
375 Mt. Pleasant Avenue
West Orange, NJ 07052

2. PRODUCT NAMES: Follistim-AQ (follitropin beta injection) Cartridge
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 833 IU hFSH/mL in a glass cartridge for subcutaneous administration
4. METHOD(S) OF STERILIZATION: _____
5. PHARMACOLOGICAL CATEGORY: Gonadotropin
6. DRUG PRIORITY CLASSIFICATION: Standard

B. 1. DATE OF INITIAL SUBMISSION: January 28, 2000

2. DATE OF AMENDMENT: November 21, 2000

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: May 11, 2000

C. REMARKS: This review deals with the applicant's responses to deficiencies in their original application.

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

Bryan Riley, Ph.D.

cc: NDA 21-211
HFD 580/Consult File
HFD 580/E. DeGuia
HFD 580/T. Rumble
HFD 580/M. Rhee
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 12/5/00
R/D initialed by: P. Cooney,

1 Page(s) Withheld

 x § 552(b)(4) Trade Secret / Confidential

 § 552(b)(4) Draft Labeling

 § 552(b)(5) Deliberative Process

/s/

Bryan Riley
1/8/01 11:07:18 AM
MICROBIOLOGIST

Peter Cooney
1/8/01 02:10:51 PM
MICROBIOLOGIST

D. G. W. A.

OCT 26 2000

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

25 October 2000

A. 1. NDA 21-211

SPONSOR Organon, Inc.
375 Mt. Pleasant Avenue
West Orange, NJ 07052

2. PRODUCT NAMES: Follistim-AQ (follitropin beta injection) Cartridge
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 833 IU hFSH/mL in a glass cartridge for subcutaneous administration
4. METHOD(S) OF STERILIZATION: _____
5. PHARMACOLOGICAL CATEGORY: Gonadotropin
6. DRUG PRIORITY CLASSIFICATION: Standard

- B. 1. DATE OF INITIAL SUBMISSION: January 28, 2000
2. DATE OF AMENDMENT: NA
 3. RELATED DOCUMENTS:
 4. ASSIGNED FOR REVIEW: May 11, 2000

C. REMARKS: This drug was previously approved as a lyophilized product (NDA 20-582).

D. CONCLUSIONS: This submission is approvable pending resolution of microbiology deficiencies. Please see "Microbiologist's List of Deficiencies" at the end of this review.

Bryan Riley 10-25-00

Bryan Riley, Ph.D.

PRC 10/26/00

cc: NDA 21-211
HFD 580/Consult File
HFD 580/E. DeGuia
HFD 580/T. Rumble
HFD 580/M. Rhee
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 10/25/00
R/D initialed by: P. Cooney,



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