

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-582

MICROBIOLOGY REVIEW(S)

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

19 December 1996

A. 1. NDA 20-582

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

2. PRODUCT NAMES: Follistim [follitropin (rDNA origin) for injection]

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Lyophilized product of 75 IU or 150 IU of Follicle Stimulating Hormone (FSH) activity per 2 mL vial. The reconstituted product is injected intramuscularly or subcutaneously.

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Gonadotropin

6. DRUG PRIORITY CLASSIFICATION: 3S

B. 1. DATE OF INITIAL SUBMISSION: 10 January 1996

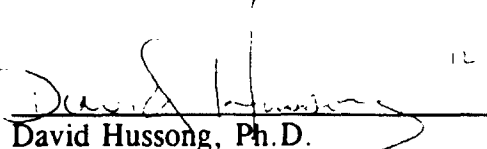
2. DATE OF AMENDMENT: 22 November 1996

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 5 December 1996

C. REMARKS: This amendment responds to deficiencies from Microbiologist's Review #1. The division (HFD-580) requests a review completion date of December 20.

- D. CONCLUSIONS: The application is recommended for approval for reasons of sterility assurance. Specific comments are provided in section "E."


David Hussong, Ph.D.

12/19/96

ATC 12/20/96

cc:

HFD 160/Consult File
HFD 580/CSO/L. Pauls
HFD 510/Review Chemist/D.-G. Wu
HFD 805/Consult File
HFD 805/D. Hussong

Drafted by: D. Hussong, 12/19/96
R/D initialed by: P. Cooney

Filename, c:\d\nda\20-592.rv2

SEP 13 1996

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

13 September 1996

A. 1. NDA 20-582

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

2. PRODUCT NAMES: Follistim [follitropin (rDNA origin) for injection]

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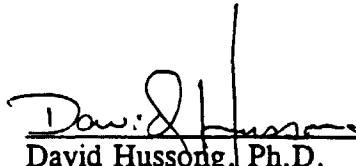
2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 22 January 1996

C. REMARKS: The submission for microbiology review was heavily cross referenced and poorly narrated. The information provided consisted of 13 volumes and nearly 6000 pages of compiled SOPs and internal reports. These could have been equally informative in 300 pages of supported narrative. Portions of the submission were very similar to NDA 20-328 (Humegon), and these sections were not reviewed again, but were accepted based on the recent review of Humegon.

- D. CONCLUSIONS: The application is not recommended for approval for reasons of sterility assurance. Specific comments are provided in section "E."


David Hussong, Ph.D. 9-13-96
PAC 9/13/96

cc:

HFD 160/Consult File
HFD 580/CSO/L. Pauls
HFD 510/Review Chemist/D.-G. Wu
HFD 805/Consult File
HFD 805/D. Hussong

Drafted by: D. Hussong, 09/12/96
R/D initialed by: P. Cooney

Filename, c:\d\nda\20-592.rv1