CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-906

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #2
February 22, 2001

A. 1. **ANDA 75-906**

APPLICANT: American Pharmaceutical Partners, Inc.

2. PRODUCT NAME: Progesterone Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL; 10-mL in 10-mL multi-dose vials; I/M

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Hormone

B. 1. DATE OF INITIAL SUBMISSION: June 16, 2000

2. DATE OF AMENDMENT: January 24, 2001
Subject of this Review (Received January 25, 2001)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: February 21, 2001

C. REMARKS: The subject amendment provides for the response to microbiology deficiencies in the correspondence dated January 2, 2001.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

Nrapendra Nath 2/22/01
Nrapendra Nath, Ph. D.

2/22/01

cc:

Page(s) 1

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Micro Rev 2

2/22/01

Microbiology Comments to be Provided to the Applicant

ANDA: 75-906

APPLICANT: American Pharmaceutical Partners, Inc.

DRUG PRODUCT: Progesterone Injection, USP

A. Microbiology Deficiencies:

You have described the Action Level for the gowns and gloves of the personnel in the filling room as [redacted] urden. However, since bioburden on gloves is critical please describe the Action Level for the gloves separately.

Please clearly identify your amendment to this facsimile as RESPONSE TO MICROBIOLOGY DEFICIENCIES. The RESPONSE TO MICROBIOLOGY DEFICIENCIES should also be noted in your cover page/letter.

Sincerely yours,

Mary Fanning, M.D., Ph.D.
Associate Director of Medical Affairs
Office of Generic Drugs
Center for Drug Evaluation and Research

OFFICE OF GENERIC DRUGS, HFD-620
Microbiology Review #1
December 15, 2000

A. 1. ANDA 75-906

APPLICANT: American Pharmaceutical Partners, Inc.

2. PRODUCT NAME: Progesterone Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 50 mg/mL; I/M; 10-mL in 10-mL multi-dose vials

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Hormone

B. 1. DATE OF INITIAL SUBMISSION: June 16, 2000
Subject of this Review (Received June 19, 2000)

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: December 14, 2000

C. REMARKS: The subject drug product is manufactured by American Pharmaceutical Partners, Inc. at its Melrose Park, IL manufacturing facility. The subject drug is aseptically filled in 10-mL glass vials in the Filling

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments to be Provided to the Applicant" found at the end of this review. The above deficiencies represent a **Fax** amendment.

Nrapendra 12/19/00
Nrapendra Nath, Ph. D.

CSO 12/19/00

cc:

); V:\microrev\75-906.doc

Page(s) 13

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Micro Rev 1

12/15/00