CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75-906

ADMINISTRATIVE DOCUMENTS

APPROVAL SUMMARY PACKAGE	
ANDA #75-906 Firm: **Am. Pharmaceutical Partners, Inc.**	Drug: Progesterone Dosage: for injection Strength: 50 mg/mL
1. CGMP Statement/EIR Update Status:	EER status: **open** as of 2-22
2. Bio Study:	Acceptable 9/28/2000
3. Methods Validation - description of Dosage Form the same as the firm's:	USP DS and DP
4. Stability - Are Containers used in the Study Identical to those in the Container Section (#26)?:	Containers: type lass vials closures Identical?: yes
5. Labeling:	Approval 2-12-2001.
6. Sterilization Validation (if applicable):	Micro acceptable 2/22/01
7. Size of *Bio/Test Batch* (Firm's source of Bulk DS satisfactory?):	DMF sat. Source: Size:
8. Size of Stability Batches (If different from bio batch were they mfg. *via* the same process?):	Size: Same: yes
9. Proposed Production Batch (Manufacturing process the same as Bio/Stability batch?):	Size: Same: yes
10. List of DP and DS specifications? Composition listed?	Yes
[signed at AP level]	*R.W. Trimmer, Ph.D.* 2-27-2001 *D.S. Gill, Ph.D.* 2-27-2001 Malcolm for 3/5/01

REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH

ANDA Number: 75-906 **Date of Submission: June 16, 2000**
Applicant's Name: American Pharmaceutical Partners, Inc.
Established Name: Progesterone Injection USP, 50 mg/mL - 10 mL multiple dose vials
Labeling Deficiencies:

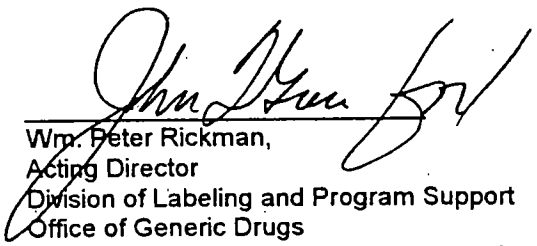
1. CONTAINER (10 mL) - Increase the prominence and conspicuousness of the established name and strength.
2. CARTON (1 x 10 mL) - Satisfactory in draft.
3. INSERT
   a. PRECAUTIONS (General)
      i. Delete the paragraph which begins, " Studies of the addition of a progestin product...".
      ii. Revise the first sentence of the next paragraph to read as follows:

      There are possible risks which may be associated with the use of progestin treatment, including adverse effects on carbohydrate and lipid metabolism.
   b. PRECAUTIONS (Carcinogenesis, Mutagenesis, Impairment of Fertility) - First sentence- Revise "Medroxy-progesterone" to read "Medroxyprogesterone".
4. PATIENT INFORMATION LEAFLET- Satisfactory in draft.

Please revise your labels and labeling, as instructed above, and submit 12 copies of final printed labels and labeling.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes- http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.



Wm. Peter Rickman,
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research

ANDA 75-906

American Pharmaceutical Partners, Inc. AUG 8 2000
Attention: Michael Lisjak
2045 North Cornell Avenue
Melrose Park, IL 60160

Dear Sir:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Progesterone Injection USP, 50 mg/mL, 10 mL vials

DATE OF APPLICATION: June 16, 2000

DATE (RECEIVED) ACCEPTABLE FOR FILING: June 19, 2000

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Michelle Dillahunt
Project Manager
(301) 827-5848

Sincerely yours,

Wm Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research