

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-756

MICROBIOLOGY REVIEW(S)

REVIEW FOR HFD-580
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGISTS REVIEW OF SUPPLEMENT
9 May 1997

A. 1. NDA 20-756

APPLICANT: Columbia Laboratories
Rockville Center, NY

2. PRODUCT NAMES: Crinone 4% and 8% (progesterone gel)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
Gel for vaginal application.

4. METHODS OF STERILIZATION:
The product is not a sterile preparation, but, conforms to microbial limit specifications.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is used for treatment of secondary amenorrhea and abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer.

B. 1. DATE OF INITIAL SUBMISSION: 23 July 1996

2. DATE OF AMENDMENT: (none)

4. ASSIGNED FOR REVIEW: 7 May 1997

C. REMARKS: The application is for a vaginal gel used in the treatment of amenorrhea. As a product intended for vaginal application it is not produced as a sterile product, but should conform to microbiological specifications. These specifications are reviewed here.

manufactures both the 4% and 8%
bulk progesterone gel. The product is packaged in
single-use, sealed applicators.

Columbia Labs, NDA 20-756; Crinone® (Progesterone gel), Microbiologist's Review #1

The applicant states that in the future a 36 month expiry period will be sought. A complete PET testing data package should be presented at that time indicating efficacy of preservation for the entire period.

D. CONCLUSIONS:

The submission is recommended for approval on the basis of microbial limits and preservative efficacy.


Paul Stinavage, Ph.D. 9 May 1997

cc: Original NDA 20-756
HFD-805/Stinavage/Consult File
HFD-580/Div File/L. Pauls/D. Moore

PAC 5/9/97

Drafted by: P. Stinavage, 9 May 1997
R/D initialed by P. Cooney