

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-843

CHEMISTRY REVIEW(S)

Moore

FEB 2 1998

**DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG PRODUCTS (HFD-580)
REVIEW OF CHEMISTRY MANUFACTURING AND CONTROLS**

NDA # 20-843 Chemistry Review # 1 Review Date: 2-2-98
SUBMISSION TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE

Original	3-10-97	3-11-97	3-24-97
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NAME AND ADDRESS OF APPLICANT

Schering Corporation
2000 Gilling Hill Road
Kenilworth, NJ 07033

DRUG PRODUCT NAME

Proprietary: Prometrium[®]
Non-proprietary/USAN: Progesterone, USP Capsules
Compendium: does not apply
Code name/number: None
Chem. Type/Ther. Class: 3 S

ANDA SUITABILITY PETITION/DESI/PATENT STATUS:

N/A

PHARMACOL. CATEGORY/INDICATION: Prometrium[®] is indicated for prevention of endometrial hyperplasia in non-hysterctomized post-menopausal women who are receiving conjugated estrogen tablets.

DOSAGE FORM: Capsules

STRENGTHS: 100 mg capsules

ROUTE OF ADMINISTRATION: Oral

DISPENSED: By prescription

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT.:

Pregn-4-ene-3,20-dione
C₂₁H₃₀O₂, Molecular Weight: 314.47

SUPPORTING DOCUMENTS: DMF

NDA19-781, V. 2.2, pages 1-44; NDA 19-781, July 29, 1996 amendment.

RELATED DOCUMENTS

19-781

CONSULTS

1. EER was sent on 4-11-97. The response is back from compliance with satisfactory results of the inspections on 4-18-97 based on profile.

REMARKS/COMMENTS

The application was declared fileable on 4-8-97. The NDA 19-781 is indicated for the treatment of secondary amenorrhea in premenopausal women. The NDA 20-843 is indicated for the prevention of endometrial hyperplasia in non-hysterectomized post-menopausal women who are receiving conjugated estrogen tablets.

CONCLUSION AND RECOMMENDATIONS

The Chemistry Manufacturing and Control information in NDA 20-843 was reviewed earlier with NDA 19-781 and found satisfactory. The stability results were updated and cross referenced in this NDA. The stability data is satisfactory. The application is approvable pending changes in labeling.

cc: NDA original
HFD-580/A. K. Mitra/2-2-98
HFD-580/M. J. Rhee
HFD-580/D. Moore
R/D. Init. By-

mpc 2/2/98

/S/

Amit K. Mitra, Ph.D

12-16-98