

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-527/S-017

PHARMACOLOGY REVIEW(S)

Date: April 11, 2001

NDA 20-527 S-017

Drug: Prempro/Premphase

Sponsor: Wyeth Ayerst

Pharmacology Teamleader Memo

The wording under the Carcinogenesis, Mutagenesis, Impairment of Fertility and Pregnancy sections of the label for NDA 20-527 S-017 are satisfactory as amended on April 11, 2001. No additional changes are necessary.

Alex Jordan, PhD

NDA 20-527 S-017
HFD-580

**APPEARS THIS WAY
ON ORIGINAL**

REVIEW AND EVALUATION OF PHARMACOLOGY/TOXICOLOGY DATA:

KEY WORDS: Conjugated estrogen, medroxyprogesterone acetate

Reviewer Name: Krishan L. Raheja, D.V.M., Ph.D.

Division Name: DRUDP

HFD#: 580

Review Completion Date: 3-23-2001

IND/NDA number: NDA 20-527

Serial number/date/type of submission: S-017/ 6 -15 - 2000

Sponsor (or agent): Wyeth-Ayerst Research

Drug: Conjugated estrogens and medroxyprogesterone acetate combination tablets 0.45 mg CE/1.5 mg MPA and 0.3 mg CE/1.5 mg MPA.

Relevant INDs/NDAs/DMFs: NDA 20-527

Drug Class: estrogen/progestin

Indication: Vasomotor symptoms

Clinical formulation: tablets

Route of administration: oral

Labeling Review (NDA): Labeling is similar to approved labeling for higher dose levels under NDA 20-527

RECOMMENDATIONS: Since the doses of conjugated estrogens and medroxyprogesterone acetate proposed in this supplement are lower than those already approved for this combination and as the labeling is similar to previously approved labeling, Pharmacology has no P/T concerns and recommends approval of the NDA for the proposed indication.

Reviewer signature/team leader signature [Concurrence/Non-concurrence]

Reviewer: Krishan L. Raheja

Team leader: Alex Jordan

cc:

NDA 20-527/S-017

HFD-580

HFD-580/A.Jordan/K.Raheja/D.Moore

N20527.017

/s/

Krishan L. Raheja
3/23/01 02:20:47 PM
PHARMACOLOGIST

Alexander W. Jordan
3/26/01 07:24:23 AM
PHARMACOLOGIST

APPEARS THIS WAY
ON ORIGINAL

NDA 20-527/S-017

Conjugated estrogens and medroxyprogesterone acetate tablets, 0.3 mg/1.5 mg and
0.45 mg/1.5 mg

Wyeth-Ayerst Laboratories, Inc.

DSI memo regarding GLP inspection

No GLP inspection was required for this efficacy supplemental application.

**APPEARS THIS WAY
ON ORIGINAL**

NDA 20-527/S-017

Conjugated estrogens and medroxyprogesterone acetate tablets, 0.3 mg/1.5 mg and
0.45 mg/1.5 mg

Wyeth-Ayerst Laboratories, Inc.

Statistical Review of Carcinogenicity Studies

No statistical review was performed because higher dosage strengths of this product have been previously approved.

**APPEARS THIS WAY
ON ORIGINAL**

NDA 20-527/S-017

Conjugated estrogens and medroxyprogesterone acetate tablets, 0.3 mg/1.5 mg and
0.45 mg/1.5 mg

Wyeth-Ayerst Laboratories, Inc.

CAC/ECAC report

No CAC/ECAC report was made for this efficacy supplemental application because higher dosage strengths have previously been approved.

**APPEARS THIS WAY
ON ORIGINAL**