CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

85239

MEDICAL REVIEW

REVIEW OF AMENDMENT, FPL

DATE COMPLETED: 1-17-79 ANDA #: 85-239

CO. NAME: Chromalloy Pharmaceuticals, Inc.

NAME OF DRUG: Estrone Suspension 5 mg/ml.

DATE OF SUBMISSION: 4-21-78

TYPE OF SUBMISSION: Resubmission - reply to FDA letter 11-9-77

CLINICAL EVALUATION:

1. Review of Studies:

Pertinent data is to be reviewed by the chemist.
Bio requirement - not required.
Full manufacturing information.

2. Review of Labeling:

Container labeling: Satisfactory
5 mg/ml. vials of 10 ml. (multiple dose)

Insert labeling: not submitted

*PPI 3-10-78 letter (firm) re "How Supplied" section.
FDA policy: PPI, when given to patients, will contain approved products only.

PPI is acceptable Aug. 1977 except for above.

CONCLUSION: PPI is acceptable Aug 1977 except for above. Labeling is satisfactory for container labels.

RECOMMENDATIONS: The firm is to be so notified.

/S/

V.V. Karusaitis, M.D.

REVIEW OF RESUBMISSION

DATE COMPLETED: 4-17-78

ANDA #: 85-239

CO. NAME: Chromalloy-Glogau Labs., Div.
Glendale, AZ 85301

NAME OF DRUG: Estrone Suspension, 5 mg/ml.

DATE OF SUBMISSION: 3-27-78

TYPE OF SUBMISSION: Resubmission - reply to FDA letter 1-6-78

CLINICAL EVALUATION:

1. Review of Studies:

   Bio requirement - not required

   Pertinent data is to be reviewed by the chemist.

2. Review of Labeling:

   Container labels: satisfactory

   Insert labeling: Satisfactory
   PPI: Aug. 77 - satisfactory

   Question need for "How Supplied" section. Statement is acceptable (3rd paragraph).

CONCLUSION: PPI labeling is satisfactory.

RECOMMENDATIONS: The firm is to be so notified.

/S/

V.V. Karusaitis, M.D.

REVIEW OF RESUBMISSION F.P.L.

DATE COMPLETED: 12-1-77

ANDA #: 85-239

F.R. DATE: 7-22-77

CO NAME AND ADDRESS:
Chromalloy Pharmaceuticals, Inc.
Glendale, AZ 85301

NAME OF DRUG: Estrone Aqueous Suspension 5 mg/ml

DATE OF SUBMISSION: 10-31-77

TYPE OF SUBMISSION: Resubmission: (Reply to FDA letters 10-28-77)

CLINICAL EVALUATION:

1. Review of studies
   Pertinent data is to be reviewed by the chemist
   Bioavailability requirement: Not required

2. Review of labeling:

   a. Container labels: Not submitted
      "PPI

   b. Insert labeling: Satisfactory
      Date: August 1977
      PPI

CONCLUSION: Labeling is satisfactory

RECOMMENDATIONS: The firm is to be so notified

/S/
V.V. Karusaitis, M.D.

cc:
Dup

REVIEW OF RESUBMISSION, FPL

DATE COMPLETED: 7-21-77

ANDA #: 85-239

CO. NAME: Carter-Glogau Labs. Div.
Glendale, AZ 85301

NAME OF DRUG: Estrone Aqueous Suspension 5 mg/ml.

DATE OF SUBMISSION: 6-28-77

TYPE OF SUBMISSION: Resubmission - reply to FDA letter 4-19-77

CLINICAL EVALUATION:

1. Review of Studies:

   Pertinent data is to be reviewed by the chemist.
   Bio requirement - not required.

2. Review of Labeling:

   a) container labeling: Satisfactory MOR 7-16-77

   b) Insert labeling: Satisfactory
      date: May 77

CONCLUSION: Labeling is satisfactory.

RECOMMENDATIONS: The firm is to be so notified.

/S/
V.V. Karusaitis, M.D.

cc:dup

REVIEW OF RESUBMISSION

DATE COMPLETED: 3-22-77

ANDA #: 85-239

F.R. DATE: 10-29-76

CO. NAME: Chromalloy-Glogau Labs. Div.
Glendale, AZ 85301

NAME OF DRUG: Estrone Suspension

DATE OF SUBMISSION: 12-9-76

TYPE OF SUBMISSION:

CLINICAL EVALUATION:

1. Pertinent material is to be reviewed by the chemist.

2. Review of Labeling:

   a) Container labels: Satisfactory
   10 ml. vials (MOR 7-16-76)
   5 mg/ml.
   I.M. USe

   b) Insert labeling: unsatisfactory
   Supply supportative data for Dosage regime for "Postpartum breast engorgement.

   Dosage levels: Send current guidelines

CONCLUSION: Insert labeling is unsatisfactory for the safe and effective use of this product as noted above.

RECOMMENDATIONS: The firm is to be so notified.

/S/
V,V. Karusaitis, M.D.

cc:dup

* ESTRONE SUSPENSION 2 mg/ml
5 mg/ml I.M.

DOSAGE:

Theelin
Parke-Davis
NDA 3-977

Estrogenone
Kremers-Urban
NDA 1-543
-Discontinued

* LABELING GUIDELINES (DOSAGE)

Replacement Therapy of Estrogen-Deficiency Associated Conditions

Initial relief of symptoms may be achieved through the administration of 0.1 mg. to 1 mg. of estrone weekly in single or divided doses. Some patients may require 0.5 mg. to 2 mg. weekly.

Senile Vaginitis and Kraurosis Vulvae

Will generally respond to injection of 0.1 mg. to 0.5 mg. of estrone two or three times weekly.

Abnormal Uterine Bleeding Due to Hormone Imbalance

May respond to brief courses of intensive estrogen therapy. Dosage in the range of 2 mg. to 5 mg. daily for several days.

For palliation in prostatic cancer, estrone may be employed at a dosage level of 2 mg. to 4 mg. two or three times weekly. If a response to estrogen therapy is going to occur, it should be apparent within 3 months of the beginning of therapy. If a response does occur, the hormone should be continued until the disease is again progressive.

/S/
V.V. Karusaitis, M.D.