

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

85239

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER

85-239

DATE APPROVAL LETTER ISSUED

FEB 24 1979

TO:

Press Relations Staff (HFI-40)

FROM:

Bureau of Drugs

Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered on label.

ORIGINAL ABBREVIATED

TYPE OF APPLICATION

ORIGINAL NDA SUPPLEMENT TO NDA ABBREVIATED ORIGINAL NDA SUPPLEMENT TO ANDA

CATEGORY

HUMAN VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG.

Estrone

DOSAGE FORM

Injectable Suspension

HOW DISPENSED

RX OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

Estrone 5 mg./ml.

NAME OF APPLICANT (Include City and State)

**Chromilly Pharmaceuticals, Inc.
Glendale, AZ 85301**

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

estrogen

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME

majarski

DATE

FORM APPROVED BY

NAME

JTmever

DATE

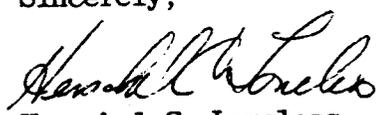
85-239

HERSCHEL C. LOVELESS
7523 17TH STREET, N.W.
WASHINGTON, D. C. 20012

June 1, 1978

TO WHOM IT MAY CONCERN:

This is to advise that the undersigned
is no longer associated with Chromalloy
American Corporation, Chromalloy Pharmaceuticals,
Inc., or any units of these corporations.

Sincerely,

Herschel C. Loveless

HCL/jhr

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 4-12-77
FROM: <i>JS</i> (thru J.L. Meyer)		OFFICE HFD-530
TO: Mr. David H. Bryant, Office of Compliance		DIVISION HFD-322
SUBJECT: Inspection Request		

SUMMARY

In connection with AIDA - *85-239*
for: *Estrone Aqueous Suspension 2mg./ml.; 5mg/ml*

Applicant: *Carter-Glozen Laboratories Division
Chromalloy Pharmaceuticals, Inc.
Glendale, AZ 85301*

AF -

REQUESTED:

- 1. Evaluation of compliance with CGMP for:
 - a. The applicant
 - b. Others

- 2. Recommendation for approval/disapproval of the application/
communication/supplement, based on your evaluation of compliance
with CGMP

REMARKS: