CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

85239

APPROVAL LETTER

NDA 85-239

FEB 21 1979

Chromalloy Pharmaceuticals, Inc.
Carter-Glogau Laboratories Division
Attention: Samuel M. Fainberg, Ph.D.
5160 W. Bethany Home Road
Glendale, AZ 85301

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Estrone Suspension, 5 mg/ml. - Sterile.

Reference is also made to your amendment s dated April 21, 1978, May 12, 1978, September 12, 1978, January 18, 1979 and January 26, 1979.

The product will carry a current 24 month expiration term.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application, requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

An Abbreviated New Drug Application is approved on the basis of a determination that the subject drug is as safe and as effective as the referenced New Drug Application product. Claims of superior safety or efficacy for an Abbreviated New Drug Application product cannot be made unless such superiority has been demonstrated by adequate and well controlled studies which have been submitted to and approved by FDA.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

2/21/79

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements

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