

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20375/S012

APPROVAL LETTER

JUN 11 1998

Berlex Laboratories, Inc.
Attention: Mr. Geoffrey P. Millington
Manager, Drug Regulatory Affairs
340 Changebridge Road
P. O. Box 1000
Montville, NJ 07045-1000

Dear Mr. Millington:

Please refer to your supplemental new drug application dated May 27, 1998, received May 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara® (estradiol transdermal system).

We further refer to your telephone conversations between the FDA and representatives of your firm on June 9, and 10, 1998.

The User Fee goal date for this application is November 28, 1998.

The supplemental application provides for a change in the expiration date of the drug products from 24 to 36 months.

We have completed the review of this supplemental application and it is approved with the following stipulations:

1. The expiration dates of the 0.05 and 0.075 mg/day strengths will be 36 months and 24 months respectively; and
2. when the 36-month stability data for the third lot of 0.1 mg/day strength is available at the end of June, the data will be submitted to the Agency for review. If the stability data are satisfactory, then the data can be reported in the Annual Report and the expiration date of the 0.1 mg/day strength system can be extended to 36 months.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Diane Moore, Project Manager, at (301) 827-4260.

Sincerely,

JSI 6/11/98

Moo-Jhong Rhee, Ph.D.
Chemistry Team Leader
Division of New Drug Chemistry II
@ Division of Reproductive and Urologic Drug
Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:

Original NDA 20-375
HFD-580/Div. Files
HFD-580/CSO/D.Moore
HFD-580/LRarick/MMann/MRhee/AMitra
HFD-820/DNDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: dm/June 10, 1998/n20375S012AP

Concurrence:

TRumble, AMitra 06.10.98/MRhee, DShames 06.11.98

APPROVAL (AP)

JSI 6/11/98