

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number:NDA 20375/S005**

**APPROVAL LETTER**

MAY 17 1996

NDA 20-375/S-005

Berlex Laboratories, Inc.  
Attention: Ms. Jo-Ann M. Ruane  
Manager  
300 Fairfield Road  
WAYNE NJ 07470

Dear Ms. Ruane:

Please refer to your January 31, 1996, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara (estradiol transdermal system).

This supplemental application provides for a packaging site change for an approved secondary packager of the drug product.

We have completed the review of this supplemental application and it is approved.

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 Ms. Christina Kish at 310-443-3520.

Sincerely yours,

/S/

5/17/96

Helen W. Davies, Ph.D.  
Chemistry Team Leader I, DNDC II  
Division of Metabolism and  
Endocrine Drug Products (HFD-510)  
Office of New Drug Evaluation II  
Center for Drug Evaluation and Research

cc:  
Orig. NDA  
HFD-510  
DISTRICT OFFICE  
HFD-80  
HFD-510/HDavies  
HFD-510/CKish/5.2.96/n20375ap.s5  
concurrences:HDavies 5.7.96/EGalliers 5.16.96  
SUPPLIMENT APPROVAL (S/AP)