CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20375/S007

APPROVAL LETTER

NDA 20-375/S-007

SEP 16 1997

Berlex Laboratories
Attention: Ms. Sharon W. Brown
Associate Director
Drug Regulatory Affairs
340 Changebrideg Road
P.O. Box 1000
Montville, NJ 07045-1000

Dear Ms. Brown:

Please refer to your supplemental new drug application dated October 18, 1996, received October 29, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara® (estradiol transdermal system).

We acknowledge receipt of your amendment dated August 13, 1997, received August 20, 1997, submitted in response to our NA letter dated April 18, 1997. The User Fee goal date for this amendment is January 20, 1998.

This supplemental application provides for an alternate manufacturing process for the drug substance to meet tighter specifications of related substances.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

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, Consumer Safety Officer, at (301) 827-4260.

Sincerely,

/S/ 9/16/97

Moo-Jhong Rhee, Ph.D.
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