CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: NDA 20-375/S-009

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	Included	Pending Completion	Not Prepared	Not Required
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Chemistry Review(s)	X			
EA/FONSI			X	
Pharmacology Review(s)			X	
Statistical Review(s)			X	
Microbiology Review(s)			X	
Clinical Pharmacology Biopharmaceutics Review(s)	X			
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Administrative Document(s)	X			
Correspondence	X			

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Approval Package for:

Application Number: NDA 20-375/S-009

Trade Name: Climara

Generic Name:(estradiol transdermal system)

Sponsor: Berlex Laboratories, Inc.

Approval Date: March 23, 1998

Indication: Provides for an addition of an intermediate patch size of 18.75 cm.

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Application Number: NDA 20-375/S-009

APPROVAL LETTER

NDA 20-375/S-009

MAR 23 1998

Berlex Laboratories, Inc.
Attention: Mr. Geoffrey P. Millington
Manager
Drug Regulatory Affairs
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-2000

Dear Mr. Millington:

Please refer to your supplemental new drug application dated September 19, 1997, received September 24, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara® (estradiol transdermal system).

The User Fee goal date for this application is March 24, 1998.

The supplemental application provides for an addition of an intermediate patch size of 18.75cm^2.

We have completed the review of this supplemental application including the submitted draft labeling and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated September 19, 1997, with the revision listed in your amendment to the supplement dated March 12, 1998. Accordingly, the application is approved effective on the date of this letter.

Please note, an extension of the shelf life to 36 months as reported in DMF is not acceptable. A separate letter has been sent to the DMF holder outlining the deficiencies.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 20-375. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drugs become available, revision of that labeling may be required.

Should a letter communicating important information about these drug products (i.e., a "Dear Doctor" letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

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,

/S/ 3-23-98

Lisa D. Rarick, M.D.
Director
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/AMitra/MRhee/ADorantes
HFD-820/ONDC Division Director
HFD-92/DDM-DIAB
DISTRICT OFFICE

Drafted by: dm/March 17, 1998/n20375aps009.doc

Concurrence:
LPauls 03.17.98/LPauls, AMitra, MRhee, ADorantes 03.20.98/LRarick 03.23.98

APPROVAL (AP) /S/ 3/23/98