

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S008

CHEMISTRY REVIEW(S)

ORIGINAL

FEB 26 1998

**DIVISION OF REPRODUCTIVE AND UROLOGIC DRUG
PRODUCTS**

**REVIEW OF CHEMISTRY MANUFACTURING AND CONTROLS
CHEMIST'S REVIEW**

1. NDA NUMBER: 20-375
2. NAME AND ADDRESS OF APPLICANT
Berlex Laboratories, Inc.
340 Changebridge Road
P.O Box 1000
Montville, NJ 07045-1000
3. SUPPLEMENT NUMBER/DATE/DATE ASSIGNED
SCS-008/8-28-97/8-29-97
4. NAME OF THE DRUG: Climara[®] (estradiol transdermal system)
5. NONPROPRIETARY NAME: Estradiol Transdermal System
6. SUPPLEMENT PROVIDES FOR: Change in the Appearance Specification
7. AMENDMENTS/REPORTS/ DATE: None
8. PHARMACOLOGICAL CATEGORY
Estrogen
9. HOW DISPENSED
Prescription
10. RELATED IND/NDA/DMF/SUPPLEMENT
DMF
11. DOSAGE FORM : Transdermal
12. POTENCY
0.05 mg and 0.1 mg/day
13. CHEMICAL NAME AND STRUCTURE
 $C_{18}H_{24}O_2 \cdot \frac{1}{2} H_2O$
MW = 281.4

Estra-1,3,5(10)-triene-3,17 β -diol, hemi hydrate

14. COMMENTS

NDA 20-375 was approved for marketing 12.5 and 25 Cm² patches of estradiol. The drug product is manufactured under DMF by 3M.

The following changes were made:

The appearance specification has been proposed to be changed.

15. CONCLUSIONS AND RECOMMENDATIONS: Since the DMF is adequate to support this change, the supplement can be approved.

Reviewed By: ISI 2-25-98
Amit K. Mitra, Ph.D, 2-24-98

R/D INIT BY: ISI 2/26/98
Moo-Jhong Rhee, Ph.D

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NDA 20-375