

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S005

CHEMISTRY REVIEW(S)

ORIGINAL

APR 24 1996

CHEMIST'S REVIEW

1. ORGANIZATION	2. NDA NUMBER
DMEDP, HFD-510	20-375

3. NAME AND ADDRESS OF APPLICANT	4. SUPPLEMENT NUMBER, DATE
Berlex Laboratories, Inc. 300 Fairfield Road Wayne, New Jersey 07470	Supplement S005 1-31-96
6. NAME OF THE DRUG	7. NONPROPRIETARY NAME
Climara	Estradiol Trans-dermal System

9. AMENDMENTS/REPORTS, DATE

8. SUPPLEMENT PROVIDES FOR:

A packaging site change for
an approved secondary packager of the drug product

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	10. RELATED IND/NDA/DMF
Estrogen replacement	RX OTC X	

DMFs

13. DOSAGE FORM	14. POTENCY
Transdermal patch	3.9 and 7.8 mg/patch

15. CHEMICAL NAME AND STRUCTURE

 $C_{18}H_{24}O_2$

MW = 272.39

Estra-1,3,5(10)-triene-3,17-diol, (17beta)-

16. COMMENTS

has been approved (Supplement 003, submitted on 15-Mar-95, approved on 22-Sep-95) as an alternate contract packager, for secondary packaging of the drug product. This Supplement provides for a site change for was previously located at (DMF

new site is located at

DMF has filed and has authorized cross-reference to its for the new site. As stated in the review for Supplement 003, the contract packager receives pouched drug product from 3M and then places the pouches into cartons and boxes for distribution. HFD-324 has stated that the compliance status of the facility is Acceptable

17. CONCLUSIONS AND RECOMMENDATIONS

The site change is acceptable. An Approval letter should be issued for the Supplement.

18. NAME	REVIEWER SIGNATURE	DATE COMPLETED
Helen W. Davies, Ph.D.	<i>[Signature]</i>	7/24/96

DISTRIBUTION; ORIGINAL JACKET	REVIEWER	DIVISION FILE
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7/D initialed by:

N20375S5

[Signature]
4/24/96