

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S001

CHEMISTRY REVIEW(S)

ORIGINAL

APR 21 1995

CHEMIST'S REVIEW

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

3. NAME AND ADDRESS OF APPLICANT 4. SUPPLEMENT NUMBER, DATE
3M Pharmaceuticals Supplement
3M Center, Bldg. 270-3A-01 Supplement
Saint Paul, Minnesota 55144-1000 S001
6. NAME OF THE DRUG 7. NONPROPRIETARY NAME 1-23-95
Climara Estradiol Trans-dermal System

8. SUPPLEMENT PROVIDES FOR: 9. AMENDMENTS/REPORTS, DATE
1) Identifying information on the backing of the transdermal systems; 2) A minor change in the drug product manufacturing procedure - a change in the temperature range for a drying oven used in manufacture of the coated laminate.
Amendments
4-07-95,
4-19-95

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
The firm made a commitment in March 1994 to add identifying information to the backing of the transdermal systems. This Supplement provides for the addition of that information, and includes the labeling text, information on the printing ink, and stability data for printed systems. The Supplement also provides for a minor change in the drug product manufacturing procedure - a change in the temperature range for a drying oven used in manufacture of the coated laminate. CMC information for the NDA is in 3M Pharmaceuticals' DMF
Therefore all of the information to support the Supplement will be filed in DMF and is reviewed in the attached DMF review (DMF

17. CONCLUSIONS AND RECOMMENDATIONS
Information in the Supplement and in the DMF Amendments supports approval of both changes. The Supplement can be approved.

18. REVIEWER
NAME SIGNATURE DATE COMPLETED
Helen W. Davies, Ph.D. /S/ 4/21/95

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/D initialed by:
wp N20375#3
M. Chell
4/21/95