

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S003

CHEMISTRY REVIEW(S)

AUG 29 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
3M Center, Bldg. 270-3A-01
Saint Paul, Minnesota 55144-1000 Supplement S003
6. NAME OF THE DRUG 7. NONPROPRIETARY NAME 3-15-95

Climara Estradiol Trans-dermal System 9. AMENDMENTS/REPORTS, DATE

8. SUPPLEMENT PROVIDES FOR:
Addition of two contract facilities for secondary packaging of the drug product: 5-23-95

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
C₁₈H₂₄O₂
MW = 272.39
Estra-1,3,5(10)-triene-3,17-diol, (17beta)-

16. COMMENTS
The drug product is currently sealed into pouches and the pouches packaged into cartons and boxes at the 3M Pharmaceuticals facility in Northridge, California. This Supplement provides for the addition of two contract facilities for secondary packaging:

As stated in the Amendment of 5-23-95, each contractor will receive pouched drug product from 3M and will then place the pouches into cartons and boxes for distribution. has DMF has DMF for their respective facilities. Both contractors have authorized cross-reference to the DMFs. An EER was submitted (on 22-Mar-95) to HFD-324 for evaluation of the packagers. The response has been received (16-Aug-95) and states that the facilities are Acceptable.

17. CONCLUSIONS AND RECOMMENDATIONS
The additional contract facilities for secondary packaging are acceptable. The Supplement can be approved.

18. REVIEWER
NAME SIGNATURE DATE COMPLETED
Helen W. Davies, Ph.D. 8/29/95

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