

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S010

CHEMISTRY REVIEW(S)

14. COMMENTS

NDA 20-375 was approved for marketing 12.5 , 18.75, and 25 Cm² patches of estradiol. The drug product is manufactured under DMF by Both manufacturing sites were approved in the original NDA. The DMF was amended to reflect requested change
The DMF amendment was not reviewed since this is a request for removal of manufacturing site. An inspection of the manufacturing site at was requested to support this change. The inspection report is satisfactory.

The following changes were made:

The coating and mixing operation located at was removed.

15. CONCLUSIONS AND RECOMMENDATIONS: Since the inspection is satisfactory, the supplement can be approved.

ISI

Reviewed By: Amit K. Mitra, Ph.D. 6-09-98

ISI

6/10/98

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NDA 20-375