

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20375/S001

APPROVAL LETTER

APR 25 1995

3M Pharmaceuticals
Attention: Ms. Julie Krech
3M Center, Bldg. 270-3A-01
ST PAUL MN 55144-1000

Dear Ms. Krech:

Please refer to your January 23, 1995, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara (estradiol transdermal system).

We also refer to your amendment dated April 7, 1995, and your telefacsimile dated April 19, 1995.

This supplemental application provides for:

1. Identifying information on the backing of the transdermal system, and
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.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions please contact Ms. Christina Kish at (301) 443-3510.

Sincerely,

/S/ 4/24/95
Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research

NDA 20-375/S-001

Page 2

cc:

Arch NDA

HFD-510

DISTRICT OFFICE

HFD-510/HDavies/YChiu

HFD-80

HFD-510/CKish/4.21,24.95/n20375.1

Concurrences:HDavies 4.21.95/YChiu 4.22.95/EGalliers 4.22.95

SUPPL. APPROVAL