

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20375/S003

APPROVAL LETTER

NDA 20-375/S-003

SEP 22 1995

3M Pharmaceuticals
Attention: Ms. Colette L. Goderstad
3M Center, Bldg. 270-3A-01
ST PAUL MN 55144-1000

Dear Ms. Goderstad:

Please refer to your March 15, 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 correspondence dated May 23, 1995.

This supplemental application provides for the addition of two contract facilities for secondary packaging of the drug product:

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/ 9/22/95
Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Center for Drug Evaluation and Research

cc:
Arch NDA
HFD-510
DISTRICT OFFICE
HFD-510/HDavies/YChiu
HFD-80
HFD-510/CKish/9.11.95/n20375.3

Concurrences: HDavies 9.11.95/YChiu 9.12.95/EGAlliers 9.20.95

SUPPL. APPROVAL