

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number: NDA 20375/S002**

**APPROVAL LETTER**

NDA 20-375/S-02

FEB 28 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 January 26, 1995, supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Climara (estradiol transdermal system).

This supplemental application provides for the addition of \_\_\_\_\_ as a manufacturer of estradiol drug substance.

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,

*JSI 2/28/95*  
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/2.24.95/n20375.2

Concurrences:HDavies 2.24.95/YChiu 2.24.95/EGalliers 2.24.95

SUPPL. APPROVAL