CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:NDA 20375/S004

APPROVAL LETTER

NDA 20-375/S-004

OCT 10 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 April 13, 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 modifications of methods for in-process testing of estradiol rollstock during manufacture of the drug product, as described in 3M's DMF

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/

Helen W. Davies, Ph.D
Acting Supervisory Chemist I
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Arch NDA
HFD-510
DISTRICT OFFICE
HFD-510/HDavies
HFD-80
HFD-510/CKish/10.4.95/n20375.4

Concurrences: Hdavies 10.5.95/EGalliers 10.7.95

SUPPL. APPROVAL