CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S002

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Date FEB - 6 1995

NDA No. 20-375

3M Pharmaceuticals
3M Center, Bldg. 270-3A-01
St. Paul, MN 55144-1000

Attention: Colette L. Goderstad

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Climara

NDA Number: 20-375

Supplement Number: S-002

Date of Supplement: January 26, 1995

Date of Receipt: January 30, 1995

Unless we find the application not acceptable for filing, the filing date will be 60 days from the receipt date above.

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Attention: Document Control Room 14B-03
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours,

/S/

Supervisory Consumer Safety Officer
Division of Metabolism and Endocrine Drug Products
Center for Drug Evaluation and Research

FORM FDA 3217c (3/93)

3M Pharmaceuticals

3M Center, Building 270-3A-01
St. Paul, MN 55144-1000

20375 002

SUPPL SUM

SUPPLEMENT – EXPEDITED REVIEW REQUESTED

3M

(612) 736-5016

FDA SUPPLEMENT

CENTER FOR DRUG RESEARCH
REC'D
JAN 30 1995
HFD-510

January 26, 1995

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolism and Endocrine
Drug Products, HFD-510
5600 Fishers Lane
Rockville, MD 20857

ORIGINAL

Attention: **Document Control Room 14B-19**

Subject: **NDA 20-375; Climara® (estradiol transdermal system)**
SUPPLEMENT - EXPEDITED REVIEW REQUESTED
Schering AG as Manufacturer of Estradiol Drug Substance

Dear Sir/Madam:

Please refer to our New Drug Application (NDA) for Climara® (estradiol transdermal system) approved December 22, 1994.

Pursuant to 21 CFR 314.70 (b), please find enclosed in duplicate a supplement to provide for as a manufacturer of estradiol drug substance.

was originally listed as a supplier in the NDA. However, on December 12, 1994, after a telephone discussion between Ms. Christina Kish of the Division and the undersigned concerning an issue with micronization facility, was withdrawn as a supplier of estradiol. Please refer to our correspondence dated December 12, 1994.

After notification of the withdrawal, a representative from subsidiary of spoke with Mr. Mark Hackman, Associate Director, International and Technical Operations Branch on January 4, 1995, seeking clarification as estradiol is not micronized for 3M Pharmaceuticals. Mr. Hackman confirmed that had a satisfactory FDA inspection of their facility on June 17 and 21, 1994 concerning the manufacture of estradiol drug substance, and there were no outstanding issues preventing from supplying estradiol drug substance produced at the facility.

Based on this information, 3M is requesting that be approved as a supplier of estradiol. Enclosed is a DMF reference letter from authorizing the FDA to refer to DMF for estradiol drug substance on behalf of 3M Pharmaceuticals.

Please contact the undersigned if you have any questions concerning this supplemental application or if any additional information is required to expedite the reinstatement of as a supplier of estradiol drug substance.

Sincerely,

Colette L. Goderstad

Colette L. Goderstad
Regulatory Specialist

Desk Copy: **Dr. Helen Davies**
Ms. Christina Kish