CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S003

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date MAR 22 1995

NDA No. 20-375

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

Attention: Julie Krech

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Climara

NDA Number: 20-375

Supplement Number: S-003

Date of Supplement: March 15, 1995

Date of Receipt: March 16, 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

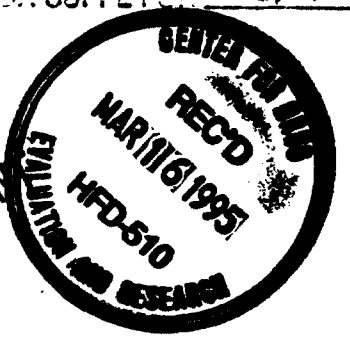
3M Pharmaceuticals

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

NDA NO. 20375 REF. NO. 003

NDA SUPPL FOR SCM

(612) 736-5353



NDA SUPPLEMENT

3M

March 15, 1995

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

ORIGINAL

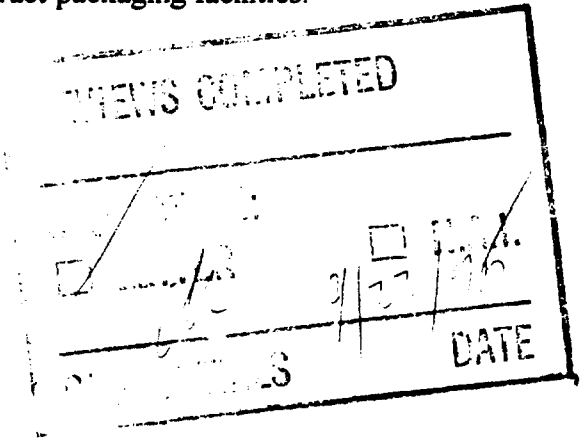
Attention: Document Control Room 14B-19

Subject: NDA 20,375; Climara® (estradiol transdermal system)
SUPPLEMENT S-003- Addition of Contract Packaging Facilities

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)(2)(vi), we hereby submit in duplicate this supplement for the addition of the following two contract packaging facilities:



Letters of Authorization for Drug Master File reference for each facility are attached. The corresponding Drug Master File numbers are provided below:

Drug Master File

Drug Master File

Please feel free to contact me if you have any questions or comments regarding the information contained in this supplement.

Sincerely,

Julie Krech

Julie Krech
Regulatory Officer

3M Pharmaceuticals

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

(612) 736-5353

ORIGINAL

SUBMISSION
SEC-003

3M

May 23, 1995

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

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

Subject: **NDA 20-375; Climara® (estradiol transdermal system)**
Response to Request for Clarification Regarding Supplement S-003- Addition of Contract Packaging Facilities

Noted - w
Chem Rev
& Team

Dear Dr. Davies:

Please refer to our New Drug Application (NDA) for Climara®, estradiol transdermal system, approved December 22, 1994, and our Drug Master File of August 31, 1992. Also refer to Supplement S-003 of March 15, 1995, for the addition of contract packaging facilities.

Per your telephone request of May 23, 1995, the following clarification is provided in regards to the function of which will serve as a secondary contract packager, as specified in supplement S-003:

Climara® (estradiol transdermal systems) that have already been packaged into foil pouches by 3M Pharmaceuticals will be received by will then place the foil pouches received into cartons and boxes, and will distribute the packaged finished product.

The above packaging function is also true for , with the exception of distribution. Finished packaged product will be shipped from for distribution.

This correspondence is submitted in duplicate to this NDA. A desk copy will be faxed to you directly. If you have any further comments or questions, please contact me at (612) 736-5353.

Sincerely,

Julie Krech

Julie Krech
Regulatory Officer