CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20375/S001

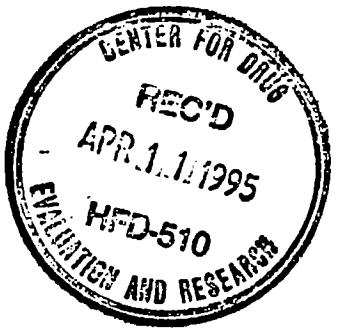
CORRESPONDENCE

3M Pharmaceuticals

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

ORIGINAL

(612) 736-5353



3M

April 7, 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

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

Subject: **NDA 20-375; Climara® (estradiol transdermal system)**
Amendment to Supplement S-001- EXPEDITED REVIEW
REQUESTED: Information on Printing Ink

Dear Sir/Madam:

Please refer to our New Drug Application (NDA) for Climara®, estradiol transdermal system, to our supplement S-001 of January 23, 1995, and to your approval letter dated December 22, 1994.

As per request of Dr. Helen Davies of March 23, 1995, the following items from are enclosed for review:

- Certificate of Analysis for
- Statement that all of the ingredients of the ink are included in 21 CFR, including CFR references for each ingredient

Also enclosed is the three month stability data for the printing ink for lots PD3713, PD3714, and PD3715. Stability on the printing ink was requested in your approval letter of December 22, 1994.

This amendment to supplement S-001 is provided in duplicate. As mentioned previously, approval of this supplement is necessary for us to launch this product, therefore expedited review of the amendment would be greatly appreciated.

If you have any comments or questions, please contact me at (612) 736-5353.

Sincerely,

Julie Krech

Julie Krech
Regulatory Officer

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I.

CSO INITIALS | DATE

3M Pharmaceuticals

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

NDA NO. [illegible] S.E. NO. [illegible]

NDA SUPPL FOR [illegible]

SUPPLEMENT -- EXPEDITED REVIEW REQUESTED

3M

(612) 736-5016

NDA SUPPLEMENT

ORIGINAL

January 23, 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

REVIEWS COMPLETED
CSO ACTION: ☐ LETTER ☐ N.A.I.
CSO INITIALS 4/27/95 DATE

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

Desk Copy: **Dr. Helen Davies**

Subject: **NDA 20-375; Climara® (estradiol transdermal system)**
SUPPLEMENT - EXPEDITED REVIEW REQUESTED
Information on Printing Ink

RECD
JAN 25 1995
HFD-510
EVALUATION AND RESEARCH

Dear Sir/Madam:

Please refer to our New Drug Application (NDA) for Climara® (estradiol transdermal system, and to your approval letter dated December 22, 1994.

As requested in your approval letter, and in accordance with 21 CFR 314.70 (b), please find enclosed in duplicate a supplement to provide for printing of identifying information on the Climara system (patch). Included is a copy of the identifying information consisting of the tradename, the established name, and the content of the active ingredient to be printed on the system. Also included is supplier and chemistry information for the printing ink and stability data for the labeled product. The printing ink is

Presently, three lots of patches printed with have been initiated on formal stability - PD3713, PD3714, and PD3715. Stability studies conducted at 40°C/75% RH, 25°C/60% RH, and 4°C have indicated that the printing present on the backing of the patch is durable and legible through 1 month at these various temperature conditions. The 1 month stability test results are not yet available for these lots.

Informal stability studies conducted on Lot 94-040 at 40°C/75% RH, 30°C, and 4°C have indicated that the printing present on the backing of the patch is durable and legible through 6 months at these various temperature conditions. The ink utilized for these studies was . This ink differs from only with respect to the percentage of propylene glycol reducer and pigment.

As discussed with Dr. Davies of the Division, a DMF reference letter is also included to provide for a minor change in the manufacturing procedure based on process validation recently completed at our facility in Northridge, CA. This change is located in an update submitted January 24, 1995, to Drug Master File entitled "Estradiol Transdermal Drug Delivery System".

If you have any questions concerning this correspondence, please call or write to me at the address indicated above.

Sincerely,

Colette L. Goderstad

Colette L. Goderstad
Regulatory Specialist