CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA20375/S010

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-375/S-010

DEC 30 1997

Berlex Laboratories, Inc.
340 Changebridge Rd.
Montville, NJ 07045

Attention: Geoffrey Millington
Manager, Drug Regulatory Affairs

Dear Mr. Millington:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Climara (estradiol transdermal system)

NDA Number: 20-375

Supplement Number: S-010

Date of Supplement: December 16, 1997

Date of Receipt: December 24, 1997

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on February 22, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Office of Drug Evaluation II
Attention: Document Control Room 17B-20
5600 Fishers Lane
Rockville, MD 20857

Sincerely, /S/

Lana L. Pauls, M.P.H.
Chief, Project Management Staff
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-375/S-010
HFD-580/Div. Files
HFD-580/CSO/

SUPPLEMENT ACKNOWLEDGEMENT

BERLEX

ORIGINAL

Drug Development & Technology
Division of Berlex Laboratories, Inc.

340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000
Telephone: (973) 276-2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NDA NO. 20-375 REF. NO. 010
NDA SUPPL FOR SCS 33

REVIEWS COMPLETED
CSO ACTION:
☑ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE 12/11/97

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
DEC 24 1997
HFD-580

Noted NAI
1/5/98

December 16, 1997

Lisa Rarick, M.D., Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation II, HFD-580
Center for Drug Evaluation and Research
Food and Drug Administration
Room 17B-45
5600 Fishers Lane
Rockville, Maryland 20857-1706

Inspection needed

Re: NDA 20-375
Climara® (estradiol transdermal system)
Special Supplement - Changes Being Effected:
Withdrawal of , mixing and coating,
all patch sizes

Dear Dr. Rarick,

Reference is made to our NDA 20-375 for Climara® (estradiol transdermal system) which was approved on December 22, 1994 and was transferred to Berlex Laboratories, Inc. from 3M Pharmaceuticals on November 2, 1995. The NDA provides for two patch sizes, 12.5 cm^2 and 25 cm^2.

Reference is also made to Drug Master File No. for Climara® (estradiol transdermal system) which incorporates Chemistry, Manufacturing and Controls information to support NDA 20-375.

Pursuant to 21 CFR 314.70(c)(1), this supplemental application provides for the removal of the mixing and coating operations for Climara® from the site

located at Climara® patches will be formulated and coated as rollstock, converted and packaged by facility is an approved Climara® manufacturing site in NDA 20-375.

The documentation to support this change is provided in the amendment submitted by to their DMF on December 10, 1997. Enclosed is a copy of the DMF amendment cover letter which authorizes the Division to review this amendment in association with this supplemental application.

Please contact the undersigned at (973) 276-2254 if you have any questions concerning this supplement.

Sincerely,

BERLEX LABORATORIES

Geoffrey P. Millington
Manager
Drug Regulatory Affairs

GPM/letter/clima032

Enclosures