CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA20375/S008

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-375/S-008

SEP - 4 1997

Berlex Laboratories, Inc.
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

Attention: June K. Bray
Director, Drug Regulatory Affairs

Dear Ms. Bray:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Climara (estradiol transdermal system)

NDA Number: 20-375

Supplement Number: S-008

Date of Supplement: August 28, 1997

Date of Receipt: August 29, 1997

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on October 28, 1997 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

375/S-008

cc:

Original NDA 20-375/S-008
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

UPS OVERNIGHT

SUPPLEMENT - EXPEDITED REVIEW REQUESTED

August 28, 1997

NDA NO. 20-375 REF. NO. 008
NDA SUPPL FOR SCE

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
5600 Fishers Lane
Room 17B-45
Rockville, Maryland 20857-1706

Noted KR 3/6/98

Re: NDA 20-375
Climara® (estradiol transdermal system)
Supplement: Change in Product Appearance Specifications

Dear Dr. Rarick,

Reference is made to our NDA 20-375 for Climara® (estradiol transdermal system). Reference is also made to the Field Alert filed by Berlex Laboratories on May 13, 1997 and to the teleconference with the Division held on May 14, 1997 concerning the need to revise the appearance specification for the product. Specifically, have been observed in the adhesive matrix of the product, and the existing specification does not allow for the presence of any

This supplemental application provides for a change in the appearance specification to allow for the presence of in the product. The justification and documentation to support this change are provided in the amendment submitted by 3M Pharmaceuticals to their DMF on August 28, 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.

Berlex is requesting an expedited review of this supplemental application pursuant to 21CFR314.70 (b)(2)(ii), as the existing appearance specification does not allow for the presence of which have been observed in marketed lots.

In addition to the Archival and Review Copies submitted herein, a Field Copy of this supplement is being provided to the FDA District Office in Parsippany, NJ. Each copy of this application contains the appropriate Field Copy certification statement and debarment certification statement.

Please contact the undersigned at (973) 276-2161 if you have any questions concerning this supplement.

Sincerely,

BERLEX LABORATORIES

June K. Bray
Director
Drug Regulatory Affairs

JKB/gks/034

Enclosures

REVIEWS COMPLETED

CSO ACTION:
☑ LETTER ☐ N.A.L. ☐ MEMO

CSO INITIALS 12/7/98 DATE