CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:NDA 20375/S005

CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Date FEB - 9 1996

NDA No. 20-375

BERLAX LABORATORIES, INC.
300 Fairfeild Road
Wayne, New Jersey 07470

Attention: Jo-Ann M. Ruane

Dear Sir/Madam:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: CLIMARA (estradiol transdermal system)

NDA Number: 20-375

Supplement Number: S-005

Date of Supplement: January 31, 1996

Date of Receipt: February 7, 1996

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on April 7, 1996 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 Metabolic and Endocrine Drug Products
Attention: Document Control Room
5600 Fishers Lane, HFD-510
Rockville, MD 20857

Sincerely yours.

/S/

Chief, Project Management Staff
Division of Metabolic and Endocrine Drug Products
Office Drug Evaluation II
Center for Drug Evaluation and Research

REVIEWS COMPLETED

CSO ACTION:

☒ LETTER ☐ N.A.L.

5/7/96

CSO INITIALS DATE

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

BERLEX

ORIGINAL

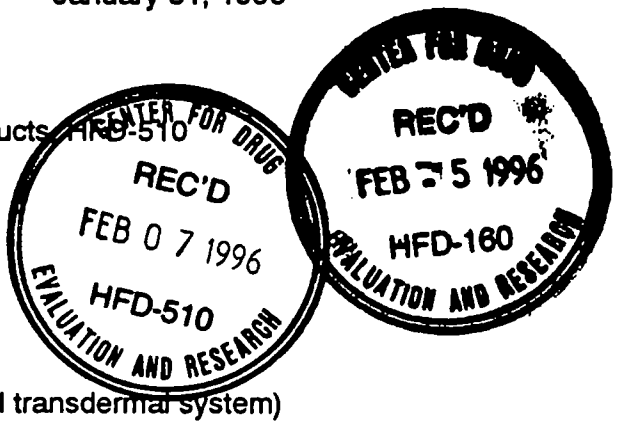
Drug Development & Technology
Division of Berlex Laboratories, Inc.

300 Fairfield Road
Wayne, NJ 07470-7358
Telephone: (201) 694-4100
Fax: (201) 694-9093

NDA 20375 SUPPL NO 005

SCN

January 31, 1996



Solomon Sobel, M.D., Director
Division of Metabolic and Endocrine Drug Products, HFD-510
Office Of Drug Evaluation II
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Re: NDA 20-375
Climara® (estradiol transdermal system)
Supplement: Change in Site of Secondary Packager

Dear Dr. Sobel,

This supplement requests approval of a packaging site change for a secondary packager of Climara® (estradiol transdermal system).

Reference is made to our New Drug Application 20-375 for Climara® (estradiol transdermal system) which was approved on December 22, 1994. This NDA was transferred to Berlex Laboratories, Inc. from 3M Pharmaceuticals on November 2, 1995.

Reference is also made to S-003, submitted on March 15, 1995 and approved on September 22, 1995, which provides for the use of Berlex Laboratories, Inc. and a contract packager, , for secondary packaging of Climara®. Included in this supplement was a letter authorizing the Agency to refer to the Drug Master File for for their facility at

Pursuant to 21 CFR 314.70(2)(vi), this supplemental application is being submitted to provide for a change in site for secondary packaging performed by , has moved their packaging operations to and has filed a Drug Master File No. for this facility. A copy of a letter authorizing the Agency to refer to DMF No. on behalf of Berlex Laboratories is attached. In addition, this site was inspected by the Philadelphia District Office on July 5 and 14, 1995. No negative observations were made and no FD-483 was issued as a result of this inspection.

Reference is also made to a letter from Robert A. Jerussi, Ph.D., Associate Director for Chemistry, CDER to

This supplement is being submitted in accordance with the requirements listed in the letter with the exception of Item 4. As clarified in a phone conversation between Dr. Jerussi and Ms. Brenda Marczi of Berlex Laboratories, Inc., the commitment to generate stability data is not required in the case of secondary packaging. The other 3 items described in the April 20, 1995 letter are addressed as follows:

1. A pre-approval supplement is being submitted herein;
2. An acceptable CGMP inspection was conducted at the new facility (as described above);
3. Pre-approval stability data are not required.

As specified in the April 20, 1995 letter from Dr. Jerussi, provided below is a list of the other NDAs which have been supplemented by Berlex or, in the case of co-marketed products, the NDA holder, to provide for this site change.

NDA Number	NDA Holder	Drug Product	Operation Performed by	Supplement Submitted	Status of Supplement
19-865	Berlex Laboratories	Betapace® Tablets	Primary packaging; unit dose blister packaging	10/30/95	Approved 12/4/95
16-647	Berlex Laboratories	Quinaglute® Tablets	Primary packaging; unit dose blister packaging	10/30/95	Approved 11/16/95

also has been provided for as a secondary packager of Tri-Levlen Tablets in Berlex intends to amend this application to provide for the change in site.

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.

If you have any questions pertaining to this supplement, please contact the undersigned at (201) 305-5123.

Sincerely,

BERLEX LABORATORIES

Jo-Ann M. Ruane

Jo-Ann M. Ruane
Manager
Drug Regulatory Affairs

JMR/007
(Enclosures (pages 00001 to 00006)