DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 22 1997

TRANSMITTED VIA FACSIMILE

Ms. Sharon Brown
Associate Director
Drug Regulatory Affairs
Berlex Laboratories, Inc.
300 Fairfield Road
Wayne, NJ 07470

RE: NDA 20-375
Climara (estradiol transdermal system)
MACMIS 5356

Dear Ms. Brown:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a certain promotional materials for Climara that are false and misleading, and, thus, is in violation of the Federal Food, Drug, and Cosmetic Act. These materials include a 1997 desk calendar (ID 96-440-6750) and a poster (ID 97ACOG-45).

Specifically, DDMAC has the following objections:

1. The poster and the cover of the calendar claim that Climara offers "benefits that last a lifetime." This claim is misleading because it is not known whether benefits from a course of estrogen replacement therapy would last a full lifetime and because Climara is not indicated to be used for the rest of a woman's natural life. According to the approved product labeling (PI) there is a risk of endometrial cancer and other malignancies that increases with the duration of use of Climara. Further, the Dosage and Administration section of the PI states that attempts to taper or discontinue the medication should be made at 3- to 6-month internals.

2. Within the calendar (e.g., opposite March 1997) there is a claim regarding a cardiovascular benefit from prolonged use of Climara (e.g. "when used 6 months or longer"). This claim is false, misleading, and contradictory to the PI for two reasons: (1) The PI suggests that the medication be tapered or discontinued within a 6-month period and

(2) the cardiovascular benefits of estrogen replacement therapy in postmenopausal women has not been proven.

In order to address DDMAC's objections to this promotional campaign, DDMAC requests that Berlex take the following actions:

1. Immediately cease further distribution of this calendar and other materials with similar messages.

2. Provide DDMAC, in writing, with Berlex's intent to comply with the above. This response should include a list of all violative promotional materials and Berlex's methods for discontinuing their use.

Berlex's response should be received no later than August 5, 1997. If you have any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5356 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications