DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JUL - 9 1998

TRANSMITTED VIA FACSIMILE

Ms. Nancy A. Konnerth
Senior Regulatory Associate, Drug Regulatory Affairs
Berlex Laboratories, Inc.
340 Changebridge Road
P.O. Box 1000
Montville, NJ 07045-1000

RE: NDA#20-375
Climara (estradiol transdermal system)
MACMIS 6501

Dear Ms. Konnerth:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a detailing aid (ID #97-440-0070) for Climara that is false and misleading, and, thus, is in violation of the Federal Food, Drug, and Cosmetic Act.

Specifically, DDMAC has the following objections:

1. The comparative information on weekly estrogen delivery, on the front of this detailing piece, is false and misleading because there are no clinically significant differences among the patches. Climara, Fempatch, Alora, and Vivelle are all considered to have the same, essentially superimposable delivery. Thus, Berlex's presentation for Alora and Vivelle as "peak-to-trough" is inaccurate. Also, while Estraderm may deliver a profile that appears to be "peak-to-trough" relative to the others, there has been no clinically significant difference associated with this.

2. The headline "The Climara Advantage" is misleading because it implies superiority without adequate and well-controlled comparative clinical studies.

3. The detailing piece is lacking fair balance because it fails to provide sufficient emphasis for the information relating to side effects and contraindications. Instead, this information is confined to tiny print at the bottom of the back of the detailing piece.

In order to address these objections, DDMAC requests that Berlex take the following actions:

1. Immediately cease further use of detailing aid and other materials and promotional practices with the same or 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 July 23, 1998. 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 #6501 in addition to the NDA number.

Sincerely,

/S/

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