DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOI

OCT 21 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 6867

Dear Ms. Konnerth:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials and practices by Berlex Laboratories' (Berlex) for Climara that are false and misleading, and, thus, is in violation of the Federal Food, Drug, and Cosmetic Act. The materials include convention panels, displayed at the American College of Obstetrics and Gynecology *meeting held in May 1998, that portray comparative claims to Premarin* (conjugated estrogens).

Specifically, the convention panels carry bullets that claim that Climara has "efficacy equal to Premarin." There is no qualification regarding the limitations to this claim. Thus, without adequate substantiation, the claim implies that Climara may be a substitute for Premarin for all of its indications. Although Climara has been shown to be comparable in effectiveness to Premarin in controlling vasomotor symptoms of menopause, it has not been shown to be as effective as Premarin for other indications, such as osteoporosis.

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

1. Immediately cease further use of these convention panels 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 November 4, 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 #6867 in addition to the NDA number.

Sincerely,

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