DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

MAR 26 1997

TRANSMITTED VIA FACSIMILE

Michael M. Rosen, Ph.D.
Director, Regulatory Affairs
Forest Laboratories
909 Third Avenue
New York, New York 10022-4731

RE: NDA 20-375
Climara (estradiol transdermal system)
MACMIS 5058

Dear Dr. Rosen:

The Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a recent promotional campaign by that is being funded by Forest Pharmaceuticals (Forest). This campaign involves a September 1996 mailing to customers who had prescriptions for Estraderm (Ciba Geneva Pharmaceuticals). The information included in the mailing consists of a misleading representation about Climara and, thus, is in violation of the Federal Food, Drug, and Cosmetic Act.

Specifically, the letter is a promotional program by Forest to switch Estraderm users to Climara. This promotional program is misleading in that it fails to disclose that Climara has not been demonstrated to be safe and effective for, and is not indicated for, all of the uses of Estraderm. Further, the letter lacks any safety information required for fair balance.

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

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

2. Prepare a corrective letter that will be sent to all consumers that have received the mailing. This letter should contain the appropriate limitations to the indication for Climara, as well as the safety information associated with its use. Please provide DDMAC with a draft of the corrective letter for review and comment before its distribution.

3. Provide DDMAC, in writing, Forest's intent to comply with the above.

Forest's response should be received no later than April 7, 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 #5058 in addition to the NDA number.

Sincerely,

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

File Name: m5058a.nov

Drafted:	LLS	Date: 18-MAR-97
Concur w/rev:	Palmer	Date: 19-MAR-97
Concur w/rev:	Drezin	Date: 25-MAR-97
Final:	LLS	Date: 26-MAR-97

CC:
HFD-40/NDA 20-375
HFD-40/Chron/Stockbridge/Palmer

FOI STATUS: RELEASABLE

MACMIS ID #5058

MACMIS Type Code:	LETT
MACMIS Action Code:	VIOL

Close Out: NO