DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 26 1997

TRANSMITTED VIA FACSIMILE

Michael P. Bigelow
Attorney
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Re: NDA 20-815
Evista (raloxifene HCL)
MACMIS ID # 5904

Dear Mr. Bigelow:

This letter is in reference to Eli Lilly and Company's (Lilly) advertisements for its investigational new drug, Evista. The advertisements are titled "If estrogen is the answer, why are there so many questions?" and "Estrogen is good. Estrogen is bad." The advertisements appear in several consumer magazines, including the September 14, 1997, edition of the Parade magazine. The Division of Drug Marketing, Advertising and Communications (DDMAC) has determined that the materials are product-specific advertisements for a particular drug, Evista, that is under investigation and that the materials are misleading in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations.

The advertisements are misleading because they imply that an investigational drug is superior to estrogens. For example, in one advertisement, the prominent headline "If estrogen is the answer, why are there so many questions?" is followed by information about the benefits, side effects, and risks of estrogen therapy. The ad subsequently states that "Research is ongoing to find new choices for women who want to stay strong and vital in the years after menopause." DDMAC believes that this statement, immediately following the focus on the risks and perceived risks of estrogens (including the statement that "many women have serious concerns about a possible link between estrogen replacements and cancer") suggests that Lilly is developing a specific new product in this therapeutic area. Further, the presentation, as a whole, suggests that this new product will possess the positive, but not the negative,

characteristics of estrogen therapy and will be better than currently available therapies.

The regulations promulgated pursuant to the Act, 21 CFR 312.7, state that an investigational new drug may not be promoted as being safe and effective for the uses under investigation. Consistent with this regulation, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review, without making promotional claims of safety or efficacy that are prohibited by the Act.

The first method of is an institutional message or announcement. Institutional messages state that a particular drug company is conducting research in a certain therapeutic area to develop new and important drugs. The announcement should not suggest any particular drug by name or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under consideration.

The second method is a "Coming soon" announcement. "Coming soon" announcements state the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

The advertisements cited herein are not considered institutional or "coming soon" messages because they suggest promotional claims of efficacy and safety for a particular drug that is under investigation for use in the therapeutic area.

Therefore, these advertisements and similar violative promotion of Evista should be discontinued immediately. Lilly should respond to this letter by December 12, 1997, indicating its intent to comply with this recommendation. This response should include a list of all similarly violative materials and a description of the method for discontinuing their use.

If Lilly has any questions or comments, please contact the undersigned by facsimile at (301)594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #5904, in addition to the NDA number.

Sincerely,

Anne M. Reb, M.S., NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications