DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 12 1999

TRANSMITTED VIA FACSIMILE

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

RE: NDA 20-815
Evista (raloxifene HCl)
MACMIS ID# 7470

Dear Mr. Bigelow:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Evista (raloxifene hydrochloride) disseminated by Eli Lilly and Company (Lilly) that are in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. DDMAC specifically refers to a direct-to-consumer (DTC) journal advertisement that appeared in the September, 1998 issue of Health magazine and the October, 1998 issue of Prevention magazine containing the following violations:

Lack of Fair Balance

This advertisement lacks fair balance because the risk information is not presented with a prominence which is reasonably comparable with the presentation of the information relating to the claims of benefit. The claims, "Prevents osteoporosis...Lowers cholesterol...Addresses concerns about breast cancer" highlighted with bold red circles and set off by red lines connecting them to positive exclamations of "Great news... More news... A little more news" present an overwhelming emphasis on benefit. This presentation of benefit information is not adequately balanced by the presentation of risk information in running text found under statement, "Things you should know about Evista."

Overstatement of Benefit

This advertisement is misleading because it overstates Evista's benefits. By promoting "Prevents osteoporosis...Lowers cholesterol...Addresses concerns about breast cancer" with equal prominence, this advertisement implies that Evista is indicated for a broader range of uses than supported by the product's labeling. Evista is only indicated for the prevention of osteoporosis in postmenopausal women. Please note that this issue was previously discussed in our letter of February 13, 1998.

Unsubstantiated Safety Claim

The claim, "Addresses concerns about breast cancer" is misleading because it implies a certainty regarding the possible effect of Evista on breast tissue that is not adequately substantiated by the data. Lilly's inclusion of the following statement, "Importantly, women taking Evista had no increased risk of breast or uterine cancer in studies of up to 3 years" is not sufficient to overcome the misleading message that Evista is safe for women's breast tissue. This issue was addressed in our letter of February 13, 1998.

Minimization of Risk Information

This advertisement is misleading because it minimizes the increased risk of venous thromboembolic events associated with the use of Evista. The statement, "Nor should you take Evista if you've had blood clots that required a doctor's treatment, although the chance of getting them from taking Evista is rare," (emphasis added) does not convey the seriousness of the risk of developing this condition as communicated in the Contraindication and Warning sections of the labeling. Please note that this issue was also discussed in our letter of February 13, 1998.

DDMAC recommends that Lilly immediately discontinue the use of this and all other promotional materials for Evista that contain the same or similar violations. Please respond to this letter in writing within 10 days. This response should include a list of all similarly violative promotional materials and Lilly's method for discontinuing their use.

If Lilly has any questions or comments, please contact the undersigned at (301) 827-2831, 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 Lilly that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS ID #7470 in addition to the NDA number.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

Chin Koerner, M.S., M.Ed.
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