DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 2 1999

TRANSMITTED VIA FACSIMILE

Gregory G. Enas, Ph.D.
Director, U.S. Regulatory Affairs
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

RE: NDA 07-517
Tapazole (methimazole)
MACMIS #8074

Dear Dr. Enas:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional material for Tapazole (methimazole) that is lacking in fair balance or otherwise misleading. Reference is made to a convention panel displayed at the 81st Annual Endocrine Society Meeting held in San Diego on June 12-15, 1999. The dissemination of this material by, or on behalf of, Eli Lilly and Company (Lilly) violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. DDMAC requests that the use of the above referenced material and those containing the same or similar violations cease immediately.

Lack of Fair Balance

Promotional materials may be lacking in fair balance, or otherwise misleading if they fail to present information relating to side effects and contraindications, with a prominence and readability reasonably comparable to the presentation of efficacy information. The aforementioned convention panel contained the claim, "Your first choice in the treatment of hyperthyroidism" which triggers the need for balancing risk information. The approved product labeling for Tapazole includes a serious warning regarding potential agranulocytosis and lists several precautions and adverse reactions associated with the use of the drug. However, Lilly failed to include any risk information in the convention panel.

Failure to Comply with 314.81 (b)(3)(i)

Since the convention panel was not submitted on Form FDA 2253 at the time of initial dissemination, Lilly has violated the postmarketing reporting requirements of the Act.

Lilly should immediately cease using the convention panel, and all other promotional materials for Tapazole that contain the same or similar violations. Lilly should submit a written response to DDMAC, on or before July 16, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Lilly should include a list of all promotional materials that were discontinued, and the discontinuation date.

Lilly should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 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 #8074 and NDA 07-517.

Sincerely,

Michael A. Misocky R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications