DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 30 1998

TRANSMITTED VIA FACSIMILE

Ellen R. Westrick
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
P.O. Box 4, WP37C-116
West Point, PA 19486

RE: NDA 20-788
Propecia (finasteride)
MACMIS ID #6807

Dear Ms. Westrick:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a journal advertisement, disseminated by Merck & Co, Inc. (Merck), for Propecia that is in violation of the Federal Food, Drug and Cosmetic Act and applicable regulations. Specifically, DDMAC refers to a journal ad for Propecia that appears in the May 11, 1998, issue of *Time Magazine*. DDMAC objects to this ad for the following reason:

Overstatement of Efficacy

The ad is misleading because it suggests, without substantial supporting evidence, that Propecia therapy is guaranteed to prevent hair loss in men. The ad shows a man looking in a mirror, contemplating his hair loss. The mirror image is clearly a future depiction of the same man with hair loss that has progressed to a much greater extent. The headline "Starting today, you need not face the fear of more hair loss," in conjunction with these visual images, implies that taking Propecia guarantees the prevention of further hair loss. This implication overstates the efficacy of Propecia and is inconsistent with the approved product labeling (PI) for the product. For example, according to the PI, Propecia has been shown to slow hair loss ("...clinical studies demonstrated a slowing of hair loss with Propecia by patient self assessment"). Merck has not demonstrated that Propecia prevents hair from falling out. In fact, the PI states that 17% of men treated with Propecia for 24 months experienced hair loss.

In order to address these objections, DDMAC recommends that Merck take the following actions:

1. Immediately discontinue the use of this, and all other promotional materials for Propecia that contain the same or similar violations.

2. Provide to DDMAC, in writing, your intent to comply with #1 above. Your response should be received by August 11, 1998.

3. This response should include a list of all promotional materials that make the same or similar claims Merck's method for discontinuing their use.

If Merck has 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 Merck that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6807 in addition to the NDA number.

Sincerely,

Mark W. Askine, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications