DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR - 1 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 #6494

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 journal advertisements, disseminated by Merck & Co, Inc.'s (Merck), for Propecia that are in violation of the Federal Food, Drug and Cosmetic Act and applicable regulations. Specifically, DDMAC refers to the journal ads for Propecia that appear in the March 30, 1998, issue of *Time Magazine*. The ads state "One day science will create a pill for hair loss. That day is today. Available only from your doctor...." A picture of a pill, as well as the Merck logo, appears in the ads. These presentations suggest that Merck has developed a pill for the treatment of hair loss that is only available by prescription. DDMAC considers these to be product-specific ads for Propecia and objects for the following reasons:

The ads are misleading because they fail to provide adequate information regarding Propecia's approved indication and usage. Specifically, the claim "One day science will create a pill for hair loss...That day is today" implies that the drug is useful in a broader range of conditions than has been demonstrated. Propecia is indicated for a specific type of hair loss (androgenetic alopecia) and has been proven to be effective on specific areas of the head (vertex and anterior mid-scalp). Efficacy has not been established for other types of hair loss or for receding hairline in the temporal area on both sides of the head.

Further, the ads are misleading because they suggest that Propecia is indicated in a broader range of patients than has been demonstrated. Specifically, the ad implies that Propecia is useful for the treatment of hair loss in both sexes because it does not disclose that Propecia is indicated in men only and should not be used in women or children.

Finally, the ad is lacking in fair balance because there is no risk information *disclosed*.

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 April 15, 1998.

3. This response should include a list of all violative promotional materials and 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 #6494 in addition to the NDA number.

Sincerely,

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