DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FOF

TRANSMITTED VIA FACSIMILE

OCT - 8 1998

Robert Clark
Associate Director/Group Leader
Regulatory Affairs
Pfizer Inc.
235 East 42nd Street
New York, NY 10017-5755

RE: NDA # 20-759; 20-760
Trovan (trovafloxacin/alatrofloxacin) Tablets/Injection
MACMIS ID # 7096

Dear Mr. Clark:

The Division of Drug Marketing, Advertising, and Communications, (DDMAC) as part of its routine monitoring and surveillance program, has reviewed materials that are used to promote Pfizer Inc.'s (Pfizer) product, Trovan. These materials included poster KC216V98C, submitted under cover of Form FDA 2253. DDMAC finds the dissemination of this poster to be in violation of the Federal, Food, Drug, and Cosmetic Act (the Act) and the applicable regulations.

Specifically, DDMAC objects to the following:

Presentation of Risk Information

Poster KC216V98C is lacking in fair balance or otherwise misleading because it fails to provide an adequate presentation of the important risks associated with the use of Trovan. For example, the poster fails to include the information that "Liver function abnormalities and symptomatic hepatitis have been reported with long and short-term therapy in men and women; symptomatic pancreatitis has also been reported. Patients who develop symptoms consistent with hepatitis or pancreatitis should be monitored for liver and/or pancreatic function as clinically indicated." DDMAC believes this is important information for practitioners to safely use the product.

In order to address these violations, DDMAC recommends that Pfizer take the following actions:

1. Immediately discontinue the use of the aforementioned material and any other promotional materials for Trovan that contain the same or similar presentation; and
2. Provide a written response to DDMAC of your intent to comply with the above request, and a list of promotional materials containing the misleading presentation that will be discontinued.

Pfizer's response should be received no later than 10 business days from the issue date of this letter. If Pfizer 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 Pfizer that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID # 7096.

Sincerely,

Jo Ann Spearmon, Pharm.D., M.P.A.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications