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Food and Drug Administration  
Rockville MD 20857

**TRANSMITTED VIA FACSIMILE**

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

MAR 5 1999

**RE: NDA # 20-759; 20-760  
Trovan (trovafloxacin/alatrofloxacin) Tablets/Injection  
MACMIS ID # 7679**

Dear Mr. Clark:

The Division of Drug Marketing, Advertising, and Communications (DDMAC), as part of its routine monitoring and surveillance program, has reviewed a journal advertisement (KC431A98) for Trovan that appeared in the February 1999, edition of Physician Assistant Journal. DDMAC has determined that this advertisement is misleading in violation of the Federal, Food, Drug, and Cosmetic Act (the Act) and its implementing regulations.

Journal Ad KC431A98 makes representations about Trovan and therefore, in accordance with the regulations, is not a reminder advertisement. Specifically, the journal ad presents a pictorial representation of the lungs. In addition, the ad makes the claim, "over 1 million prescriptions written." These expressed and implied claims are clear representations about the product, and thus, would cause the ad to be considered a full product advertisement requiring, among other things, fair balance and a "brief summary" of the prescribing information.

In order to address this violation, 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 violations; and

2. Provide a written response to DDMAC of your intent to comply with the above request, a list of promotional materials containing the misleading presentations that will be discontinued, and the date of discontinuation.

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 # 7679 in addition to the NDA number.

Sincerely,

/s/

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