



FGT

Food and Drug Administration  
Rockville MD 20857

**TRANSMITTED VIA FACSIMILE**

SEP 24 1998

Russell W. Pelham, Ph.D.  
Director, Regulatory Affairs  
MacroChem Corporation  
110 Hartwell Avenue  
Lexington, MA 02173-3134

**RE:**

Topiglan  
MACMIS ID #7097

Dear Dr. Pelham:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Topiglan (alprostadil), disseminated by MacroChem Corporation (MacroChem), that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder. DDMAC specifically objects to an August 27, 1998, press release regarding Topiglan for the following reason:

Pre-Approval Promotion

Section 21 CFR 312.7, states, among other things, that an investigational new drug may not be promoted as being safe or effective for the uses under investigation. The press release in question is considered to be violative because it contains several claims regarding the safety and efficacy of the product. These claims include statements about the drug's specific use in the treatment of erectile dysfunction and other promotional claims, such as:

"Clinical Trial Results...Further Confirm and Extend Efficacy and Safety Profile of Topiglan."

"Topiglan Treatment is Effective and Well Tolerated with Minor Transitory Symptom of Warmth."

Russell W. Pelham, Ph.D.  
MacroChem Corporation  
IND 49-751

page 2

“With side effects limited to minor local symptoms, the potential use of Topiglan in patients with cardiovascular disease is encouraging.”

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

1. Immediately discontinue the use of this, and all other promotional materials for Topiglan that contain the same or similar violations.
2. Provide to DDMAC, in writing, Macrochem's intent to comply with #1 above. Your response should be received by October 8, 1998.
3. This response should include a list of all similarly violative promotional materials and Macrochem's method for discontinuing their use.

If Macrochem 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 Macrochem that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #7097 in addition to the IND number.

Sincerely,

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