- DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

APR - 1 1998

Kathleen J. Day
Director, Labeling and Promotion
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

RE: NDA# 20-771
Detrol (tolterodine tartrate tablets)
MACMIS ID #6493

Dear Ms. Day:

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 Detrol that are in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations. Specifically, DDMAC objects to a March 26, 1998, press release containing the following claims regarding Detrol:

"People with overactive bladder now have a medication that is both effective and well tolerated in treating their symptoms"

This claim is misleading because it suggests that Detrol is the first an only medication that is both safe and effective in treating patients with overactive bladders. There are other therapeutic options currently available that have also been proven to be safe and effective in treating the symptoms of overactive bladder.

"The availability of a new drug that is effective in the treatment of overactive bladder and is well tolerated could have a great positive impact on the way we manage those patients"

This claim is misleading because it suggests, without substantial evidence, that Detrol is safer than or better tolerated than other agents that are currently available.

Kathleen J. Day
Pharmacia & Upjohn
NDA 20-771

In order to address these objections, DDMAC recommends that Pharmacia and Upjohn take the following corrective actions:

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

2. Provide to DDMAC, in writing, Pharmacia & Upjohn's intent to comply with #1 above. Your response should be received by April 15, 1998.

3. This response should include a list of all similarly violative promotional materials and Pharmacia & Upjohn's method for discontinuing their use.

If Pharmacia and Upjohn 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 Pharmacia and Upjohn that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6493, in addition to the NDA number.

Sincerely,

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