DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB - 9 1998

TRANSMITTED VIA FACSIMILE

Robert E. Monovich
Promotion Review Manager
Pharmacia & Upjohn Company
7000 Portage Road
Kalamazoo, MI 49001

RE: NDA# 20-771
Detrusitol (tolterodine tartrate tablets)
MACMIS ID #6302

Dear Mr. Monovich:

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 Detrusitol that are in violation of the Federal Food, Drug and Cosmetic Act (the Act) and applicable regulations. Specifically, DDMAC objects to the journal advertisement (USJ 8919.00) appearing on the back cover of the February 5, 1998, issue of the *Journal of the American Medical Association*. DDMAC finds the journal advertisement violative for the following reason:

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. Therefore, DDMAC usually considers pre-approval promotion of drug products to be violative. However, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review without making promotional claims of safety or efficacy that are prohibited by the Act.

The first method of permissible pre-approval promotion is "Institutional Promotion." Institutional advertisements state that a particular drug company is conducting research in a certain therapeutic area to develop new and important drugs. The advertisement may not suggest any particular drug by name (proprietary or established) or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under consideration.

The second method of permissible pre-approval promotion is "Coming soon promotion." Coming soon advertisements announce the name of a new product

that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

The advertisement in question makes several written representations about the safety, efficacy, and intended use of an investigational new drug. For example, the ad states that "...some current prescription drugs have given patients intolerable dry mouth...So why...is there no better treatment choice for a disorder affecting millions of people? The ad continues "We [Pharmacia & Upjohn]...think treatment should not only help people with this problem, but be well tolerated. Our answer is coming soon. Watch for it. Pharmacia & Upjohn. Working on the best reason yet to treat overactive bladder." These claims not only imply that the drug is effective in treating overactive bladder, but also suggest, without substantial supporting evidence, that the drug is superior to current therapeutic options in terms of side effects. In addition, the ad states that the drug will soon be approved for use in the therapeutic area under consideration (treatment of overactive bladder).

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 February 23, 1997.

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 #6302, in addition to the NDA number.

Sincerely,

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