DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG - 1 1997

TRANSMITTED VIA FACSIMILE

William Baker
Manager, Drug Regulatory Affairs
Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, Connecticut 06877

RE: NDA 20-579
Flomax (tamsulosin HCl) capsules 0.4 mg
MACMIS #ID 5652

Dear Mr. Baker:

Reference is made to Boehringer Ingelheim Pharmaceuticals, Inc.'s (BIPI) "Coming Soon" advertisement for Flomax (tamsulosin HCl) that appears in the July 1997 issue of *Urology Times*. The Division of Drug Marketing, Advertising and Communications (DDMAC) has determined that this advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations. Specifically, the ad's visual image of flowing water makes a graphical representation relating to the efficacy of the advertised product and is not accompanied by a brief summary of prescribing information.

In addition, DDMAC has no record that BIPI submitted this promotional labeling at the time of initial dissemination under Form FDA 2253, as is required by 21 C.F.R. 314.81 (b) (3) (I).

The dissemination or publication of this journal advertisement, and all similar violative materials, should be discontinued immediately upon receipt of this letter. BIPI should respond to this letter in writing by August 14, 1997. BIPI's response should include a list of all similar violative materials and a description of the method for discontinuing their use.

If BIPI 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 BIPI that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID 5652 in addition to the NDA number.

Sincerely,

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