DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-579/S-016

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Kelly S. Billingham
Manager, Product Labeling
900 Ridgebury Road/P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated August 10, 2005, received August 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flomax® (tamsulosin hydrochloride) capsules, 0.4 mg.

We acknowledge receipt of your submissions dated September 20, September 27, and October 13, 2005.

This supplemental new drug application provides for the addition of information regarding Intraoperative Floppy Iris Syndrome (IFIS), geriatric use, and sulfa allergy.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (package insert and patient package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-579/S-016**." Approval of this submission by FDA is not required before the labeling is used.

When you issue the letter communicating this important information about IFIS (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Martin Kaufman, D.P.M., M.B.A., Regulatory Health Project Manager, at (301) 796-0928.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Daniel A. Shames

10/18/2005 01:28:39 PM