DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-579/S-020

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 11, 2006, received August 14, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flomax® (tamsulosin hydrochloride) Capsules, 0.4mg

This "Changes Being Effected" supplemental new drug application proposes changes to the **PRECAUTIONS** and **HOW SUPPLIED** sections of the package insert and to the **PATIENT PRESCRIBING INFORMATION** (PPI) to provide additional instructions for the patient who is considering cataract surgery to inform their ophthalmologist of their usage of FLOMAX for the physician's awareness and consideration of any implications for cataract surgery. The application also requests several minor editorial revisions such as converting HCL to hydrochloride.

We have 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 labeling submitted August 11, 2006.

Submit revised content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

If you issue a letter communicating important information about this drug product (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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Olga Salis, Regulatory Project Manager, at (301)796-0837.

Sincerely,

{See appended electronic signature page}

Mark Hirsch, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

Mark S. Hirsch

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