DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-579/S-021

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 18, 2006, received August 21, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flomax® (tamsulosin hydrochloride) Capsules, 0.4mg.

We also refer to your February 13, 2007, submission conveying your agreement to the Division's recommendations provided via facsimile on February 7, 2007.

This "Prior Approval" supplement provides for revisions to the **CLINICAL PHARMACOLOGY** and **PRECAUTIONS** sections of the labeling as requested by the Division on February 9, 2006.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter.

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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