DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-579/S-024

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Kelly S. Billingham
Associate Director, DRA Product labeling
900 Ridgebury Road/P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated October 31, 2007, received November 1, 2007, 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 submission June 3, 2008.

Your submission of June 3, 2008, constituted a complete response to our April 30, 2008, action letter.

This "Prior Approval Supplement" amendment supplemental new drug application provides for revisions to the patient labeling based on full prescribing information for Flomax®.

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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling.

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/S024**." Approval of this submission by FDA is not required before the labeling is used.

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

George Benson, M.D.
Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure -Labeling

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

/s/

George Benson

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