DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-579/S-025

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Terry Keyser
Manager, Product Labeling, Drug Regulatory Affairs
900 Ridgebury Road/P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Keyser:

Please refer to your supplemental new drug application dated April 29, 2009, received April 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Flomax ® (tamsulosin hydrochloride) Capsules, 0.4 mg.

We also refer you to your May 15, and June 24, 2009, amendments.

This "Changes Being Effected" supplemental new drug application provides for revisions and updated information in the **CLINICAL PHARMACOLOGY**, **WARNINGS**, **PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections.

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.

Please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 20-579/S-025**."

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-025**." Approval of this submission by FDA is not required before the labeling is used.

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

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20579	SUPPL-25	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	FLOMAX (TAMSULOSIN HCL) 0.4MG CAPSULES

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

/s/

OLGA SALIS
10/29/2009

GEORGE S BENSON
10/29/2009