DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090377

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw, Vice President
Regulatory Affairs and Compliance
30831 Huntwood Avenue
Haywood, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 29, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Tamsulosin Hydrochloride Capsules USP, 0.4 mg.

Reference is also made to our tentative approval letter dated October 2, 2009 and to your amendments dated December 15, 2008; December 3, December 7, December 9 and December 15, 2009; February 1, February 17 and February 19, 2010.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved effective on the date of this letter. The Division of Bioequivalence has determined your Tamsulosin Hydrochloride Capsules USP, 0.4 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Flomax Capules, 0.4 mg, of Boehringer Ingelheim Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The reference listed drug product (RLD) upon which you have based your application, Flomax Capules, 0.4 mg, of Boehringer Ingelheim Pharmaceuticals, Inc., is subject to a period of patent protection. As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. patent 4,703,063 (the '603

patent) is scheduled to expire on April 27, 2010 (with pediatric exclusivity added).

Your ANDA contains a paragraph IV certification to the '063 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that the '063 patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Tamsulosin Hydrochloride Capsules USP, 0.4 mg under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against IMPAX Laboratories, Inc. (IMPAX) for infringement of the listed '063 patent. You notified the agency that IMPAX complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '063 patent was brought against IMPAX in the United States district Court for the Northern District of California Oakland Division [Astellas Pharma Inc. and Boehringer Ingelheim Pharmaceuticals, Inc. v. IMPAX Laboratories, Inc., Civil Action No. C08-03466]. You have also notified the agency that the court entered a Consent Judgment acknowledging a negotiated settlement between Astellas Pharma Inc., Boehringer Ingelheim, Inc., and IMPAX Laboratories, Inc. This settlement applies to Boehringer Ingelheim's selective and limited waiver of its pediatric exclusivity to IMPAX Laboratories, Inc. for the '063 patent as of March 2, 2010, with respect to this ANDA. Concurrent with the agency's approval of this ANDA, the waiver effectively permits IMPAX Laboratories, Inc. to market Tamsulosin Hydrochloride Capsules, USP beginning on March 2, 2010, prior to the expiration of Boehringer Ingelheim's pediatric exclusivity for the '063 patent on April 27, 2010. The selective waiver also applies to Boehringer Ingelheim's exclusivity with respect to product labeling associated with the M-54 exclusivity code due to expire on June 22, 2013.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS, See 505-1(i).

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 090377***".

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90377	ORIG-1	IMPAX LABORATORIES INC	TAMSULOSIN HYDROCHLORIDE

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

/s/

ROBERT L WEST
03/02/2010
Deputy Director, for Gary Buehler