DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022460/S-003
NDA 022460/S-004
NDA 022460/S-005

SUPPLEMENT APPROVAL

GlaxoSmithKline
Attention: Linda Rebar
Director, Regulatory Affairs
2301 Renaissance Blvd., RN0420, PO Box 61540
King of Prussia, PA 19406-2772

Dear Ms. Rebar:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received June 6, 2012 (S-003), dated and received June 13, 2012 (S-004), and dated and received October 3, 2012 (S-005), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for JALYN® (dutasteride and tamsulosin hydrochloride) capsules.

We acknowledge receipt of your amendment for supplement 005, dated February 11, 2013.

The "Changes Being Effected" supplemental new drug application NDA 022460/S-003 provides for the addition of "depressed mood" to the Postmarketing Section of the labeling.

The "Prior Approval" supplemental new drug application NDA 022460/S-004 provides for changes to the Warnings and Precautions and Contraindications sections of the labeling to include changes based on recent updates to the Flomax® (tamsulosin hydrochloride) labeling.

The "Changes Being Effected" supplemental new drug application NDA 022460/S-005 provides for:

- An update to Table 1 in Section 6.1 (Adverse Reactions Clinical Trials Experience) of the labeling, with post-marketing adverse reaction information regarding the persistence of sexual adverse reactions following discontinuance of dutasteride
- The addition of "Reproductive System and Breast Disorders: Testicular pain and testicular swelling" to Section 6.2 of the Adverse Reactions Postmarketing Experience section
- Updating the Patient Information Section, "What are the possible side effects of JALYN"

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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 George Lyght, Pharm.D., Sr. Regulatory Health Project Manager, at (301) 796-0948.

Sincerely,

{See appended electronic signature page}

Hylton V. Joffe, M.D., M.M.Sc.
Director
Division of Bone, Reproductive, and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling

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

/s/

HYLTON V JOFFE
04/25/2013