DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022460 **TENTATIVE APPROVAL**

GlaxoSmithKline
Attention: Sherman N. Alfors
US Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Mr. Alfors:

Please refer to your new drug application dated and received March 20, 2009, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for dutasteride 0.5 mg/ tamsulosin hydrochloride 0.4 mg capsules.

We acknowledge receipt of your submissions dated April 1, May 5, May 12, June 16, June 23, June 30, July 16, August 19, September 22, October 2, November 10, November 12, November 24, December 22, 2009, and January 8, 2010.

This NDA provides for the use of dutasteride 0.5 mg/tamsulosin hydrochloride 0.4 mg capsules for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

We completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105. This determination is contingent upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices of the facilities used in manufacturing and testing of the drug product) and is, therefore, subject to change on the basis of any new information that may come to our attention.

Submit an amendment to this application on or after March 27, 2010, identifying changes, if any, in the conditions under which your product was tentatively approved. This information should include updated labeling, chemistry, manufacturing and controls data, and a safety update.

Failure to submit this amendment will prompt a review of the application that may result in a recission of the tentative approval letter.

The listed reference drug product upon which you base your application is subject to a period of exclusivity protection and therefore final approval of your application under section 505(c)(3) of the Act [21 U.S.C. 355(c)(3)] may not be made effective until the period has expired.

Any significant change in the conditions outlined in this NDA requires our review before final approval may be granted.

Before we issue a final approval letter, this NDA is not deemed approved. If you believe that there are grounds for issuing the final approval letter before the exclusivity expiration date, you should amend your application accordingly.

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 in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for this application because necessary studies are impossible or highly impracticable. BPH does not exist in children and recruiting children with BPH for a pediatric study would be impossible.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22460	ORIG-1	SMITHKLINE BEECHAM CORP DBA GLAXOSMITHKLINE	DUTASTERIDE/ 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/

GEORGE S BENSON
01/20/2010