DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-319/S-007

GlaxoSmithKline
Attention: Randal Batenhorst, Pharm.D.
Senior Director Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Batenhorst:

Please refer to your supplemental new drug application dated July 10, 2003, received July 11, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avodart™ (dutasteride) soft-gelatin capsules.

We acknowledge receipt of your submissions dated August 26, 2003, and February 23, 2004.

Your submission of February 23, 2004 constituted a complete response to our February 2, 2004, action letter.

This supplemental new drug application contains label revisions that provide information from the final study report of an in vitro metabolism study using therapeutically relevant dutasteride concentrations. The final report from this study meets your post-marketing study commitment cited in the approval letter dated November 20, 2001.

We 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 (text for the package insert).

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Martin Kaufman, D.P.M., M.B.A, Regulatory Project Manager, at (301) 827-4234.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Donna Griebel

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