DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-319/S-008

GlaxoSmithKline
Attention: Michele Hardy
Senior Director, U.S. Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709-3398

Dear Ms. Hardy:

Please refer to your supplemental new drug application dated November 14, 2003, received November 14, 2004, 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 November 21, 2003, January 13, July 22, August 3, 5, and 31, 2004. We also acknowledge receipt of your email dated September 9, 2004.

This supplemental new drug application provides two additional years of efficacy and safety data for the use of Avodart™ (dutasteride) soft-gelatin capsules for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate to: Improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of the need for BPH-related surgery.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and text for the patient package insert).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-319/S-008." Approval of this submission by FDA is not required before the labeling is used.

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.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Martin Kaufman, D.P.M., M.B.A., Regulatory Health 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

Enclosure

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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