DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-319/S-005

GlaxoSmithKline
Randal Batenhorst, Pharm.D.
Senior Director, US Regulatory Affairs, Urology
One Franklin Plaza
P.O. Box 7929
Philadelphia, PA 19101

Dear Mr. Batenhorst:

Please refer to your supplemental new drug application dated June 6, 2003, received June 9, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Avodart® (dutasteride) Soft-Gelatin Capsules.

This "Changes Being Effected" supplemental new drug application provides for the addition of the 30-count bottle to the **HOW SUPPLIED** section, warning statement to the 30-count bottle, the 100 tablet bottle and blisterpack and minor editorial corrections in the prescribing information.

We completed our review of this application and it 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 text for the patient package insert, immediate container and carton labels) and/or submitted labeling (package insert, patient package insert, and immediate container and carton labels submitted June 6, 2003).

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-005." Approval of this submission by FDA is not required before the labeling is used.

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 Jennifer Mercier, Regulatory Health Project Manager, at (301) 827-4244.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
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/

Daniel A. Shames

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