**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-319/S-009

GlaxoSmithKline
Attention: Michelle Hardy
Senior Director, U.S. Regulatory Affairs, Urology
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 June 24, 2005, received June 27, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avodart® (dutasteride) soft gelatin capsule.

This "Changes Being Effected" supplemental new drug application provides for the addition of expanded safety information under the PRECAUTIONS: Drug/Laboratory Test Interactions: *Reproductive Function* section of the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted with the 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Health Project Manager, at (301) 796-0928.

Sincerely,

*{See appended electronic signature page}*

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

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/s/
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Daniel A. Shames
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