DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-319/S-015

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

Dear Ms. Hardy:

Please refer to your supplemental new drug application dated October 18, 2007, received October 18, 2007, 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 changes to the **CONTRAINDICATIONS** and **ADVERSE REACTIONS**: **Postmarketing Experience** sections by adding a reference to angioedema and the term serious skin reactions under a newly added subsection titled ***Immune System Disorders***. The **DOSAGE AND ADMINISTRAION** section will be revised to expand information regarding swallowing capsules by adding the following text; "The capsule should be swallowed whole and not chewed or opened, as contact with the capsule contents may result in irritation of the oropharyngeal mucosa." This information is also expanded in the **PATIENT INFORMATION** (**PPI**) section leaflet under the heading "How should I take AVODART" by adding the following text; "Swallow the capsule whole because the contents of the capsule may irritate your lips, mouth, or throat."

In addition, all packaging components have been updated to reflect the name change of the manufacturer from Cardinal Health to Catalent Pharma Solutions.

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 an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-319/S-015**." 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Olga Salis, Regulatory Project Manager, at (301) 796-0837

Sincerely,

{See appended electronic signature page

George Benson, M.D.
Acting Deputy Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

George Benson
3/31/2008 12:59:11 PM