# CENTER FOR DRUG EVALUATION AND RESEARCH

## Approval Package for:

## *APPLICATION NUMBER:*
## 21-319

***Trade Name:*** Dutasteride Soft Gelatin Capsule, 0.5 mg

***Generic Name:*** Dutasteride

***Sponsor:*** Glaxo SmithKline

***Approval Date:*** November 20, 2001

***Indications:*** Provides for the Use of Dutasteride Soft Gelatin Capsules 0.5 mg for the treatment of symptomatic Benign Prostatic Hyperplasia in men with an enlarged prostate gland.

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| | Included | Pending Completion | Not Prepared | Not Required |
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| Approval Letter | X | | | |
| Tentative Approval Letter | | | | |
| Approvable Letter | | | | |
| Final Printed Labeling | X | | | |
| Medical Review(s) | X | | | |
| Chemistry Review(s) | X | | | |
| EA/FONSI | | | | |
| Pharmacology Review(s) | X | | | |
| Statistical Review(s) | X | | | |
| Microbiology Review(s) | X | | | |
| Clinical Pharmacology Biopharmaceutics Review(s) | X | | | |
| Bioequivalence Review(s) | | | | |
| Administrative Document(s) | X | | | |
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*APPLICATION NUMBER:*

**21-319**

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-319

GlaxoSmithKline
Attention: Munir Abdullah, Ph.D.
Director, Regulatory Affairs
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Abdullah:

Please refer to your new drug application (NDA) dated December 21, 2000, received December 21, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for dutasteride soft gelatin capsules, 0.5 mg.

We acknowledge receipt of your submissions dated January 3 and 26, March 1, April 20, May 9, 10, 15 and 24, June 15 and 25, July 2, 9, 13, 16, 20, and 26, August 7, 14 and 23, September 4, 7, 19 and 27, October 1, 4, 9, 11, 15 and 24, and November 2, 8, 13, 15, 16, 19 and 20, 2001.

This new drug application provides for the use of dutasteride soft gelatin capsules 0.5 mg for the treatment of symptomatic benign prostatic hyperplasia in men with an enlarged prostate gland.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), and the draft labeling (carton and container submitted on November 16, 2001). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 21-319." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your postmarketing study commitment in your submission dated November 15, 2001. This commitment is listed below.

Conduct a study to investigate *in vitro* metabolism using therapeutically relevant dutasteride concentrations to characterize the metabolic pathways.

| | |
|---|---|
| Protocol submission: | Within 1 month of the date of this letter |
| Study start: | Within 3 months of the date of this letter |
| Final report submission: | Within 6 months of the start of the study |

Submit clinical protocols to your IND for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments must be prominently labeled "Postmarketing Study Protocol", "Postmarketing Study Final Report", or "Postmarketing Study Correspondence."

Be advised that, as of April 1, 1999, 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 (63 FR 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Reproductive and Urologic Drug Products 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, Maryland 20857

Please submit one market package of the drug product when it is available.

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 Evelyn R. Farinas, R.Ph., M.G.A., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Florence Houn, M.D., M.P.H., F.A.C.P.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure