CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20180/S11

APPROVAL LETTER

NDA 20-180/S-011

AUG 28 1996

Merck Research Laboratories
Attention: Robert E. Silverman, M.D., Ph.D.
Director, Regulatory Affairs
Sumneytown Pike
Westpoint PA 19486

Dear Dr. Silverman:

Reference is made to your February 15, 1996, supplemental new drug application, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proscar (finasteride) Tablets.

This supplemental application provides for revisions in the package insert and detailed patient labeling as follows:

Package Insert

Redacted 1

pages of trade

secret and/or

confidential

commercial

information

We have completed the review of the draft labeling dated February 15, 1996, in this supplemental application and the application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling. Marketing the product with the changes provided for in these supplemental applications with FPL that is not identical to this draft labeling may render the products misbranded and unapproved new drugs.

Please submit sixteen copies of the FPL as soon as it is available, in no case 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 "FINAL PRINTED LABELING" for approved supplemental NDA 20-180/S-011. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact Ms. Christina Kish, Consumer Safety Officer, at (301) 827-4260.

Sincerely yours,

/S/

Lisa Rarick, M.D.
Acting Director
Division of Reproductive and Urologic
Drug Products (HFD-580)
Office of Drug Evaluation II
Center for Drug Evaluation and Research