Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

NDA 20-180/S-029

Merck & Company
Attention: Vivian Fuh, M.D.
P.O. Box 2000
Mail Drop: RY 33-200
Rathway, NJ 07065

Dear Dr. Fuh:

Please refer to your supplemental new drug application dated September 24, 2003, received September 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROSCAR™ (finasteride 5 mg).

Your submission of April 13, 2004 constituted a complete response to our March 24, 2004 action letter.

This "Changes Being Effected" supplemental new drug application provides for proposed changes to the **ADVERSE REACTIONS** section of the label to include information from the Prostate Cancer Prevention Trial (PCPT), sponsored by the U.S. National Cancer Institute (NCI), and coordinated by the Southwest Oncology Group (SWOG) regarding prostate cancers with Gleason scores of 7 to 10, as reported in the July 17, 2003 New England Journal of Medicine publication.

We 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.

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 20-180/S-029." Approval of this submission by FDA is not required before the labeling is used.

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. We are waiving the pediatric study requirement for this 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, 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 (HFD-580)
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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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