DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-180\S-020

Merck & Co., Inc.
Attention: Vivian Fuh, M.D,
Director, Regulatory Affairs
P.O. Box 2000, RY 33-200
Rahway, NJ 07065-0900

Dear Dr. Fuh:

Please refer to your supplemental new drug application (NDA 20-180/SLR 020) dated November 9, 1998 and received on November 10, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROSCAR™ (finasteride 5 mg).

We also acknowledge receipt of your subsequent submissions to NDA 20-180/SLR 020 dated May 8, 2000, May 16, 2001, December 6, 2002, and January 3, 2003 as well as the following submissions to (b)(4)--------for PROSCAR™ dated as follows:

Serial #530 (June 24, 2002/June 25, 2002)
Serial #533 (July 29, 2002/July 30, 2002)
Serial #534 (August 19, 2002/August 20, 2002)
Serial #535 (September 20, 2002/September 23, 2002)
Serial #536 (September 20, 2002/September 23, 2002)
Serial #537 (October 4, 2002/October 5, 2002)
Serial #538 (October 28, 2002/October 29, 2002)
Serial #539 (November 11, 2002/November 12, 2002)
Serial #540 (December 13, 2002/December 16, 2002)
Serial #541 (December 16, 2002/December 17, 2002)
Serial #543 (December 30, 2002/December 31, 2002)

Reference is also made to our Approvable letter, dated April 24, 2003, for NDA 20-180 SLR 020. This letter informed you that supplement 020 was approvable pending your agreement to add appropriate language to the PROSCAR™ labeling regarding the male breast cancer issue.

Reference is also made to our recent Approval letter, dated September 9, 2003, sent to you for NDA 20-180 SLR 027, which contained a revised package insert (PI) and patient package insert (PPI) that proposed the following:

1. Changes in the Labeling Section of the approved NDA to include isolated reports of male breast cancer in the ADVERSE REACTIONS, Long-Term Treatment.
2. Changes in the Information for Patients subsection of PRECAUTIONS to encourage physicians to instruct patients to promptly report any changes in their breasts, such as lumps, pain or nipple discharge, to their physician.
3. Changes consistent with those proposed in the PI under the “What you need to Know while taking PROSCAR” section of the PPI.

Based on this approval of NDA 20-180/ S 027, your supplement application NDA 20-180/S 020 is also approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. The FPL must be identical to the package insert and patient package insert labeling approved for NDA 20-180/S 027 on September 9, 2003. 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/SLR 020." 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, 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 Jean King, M.S., R.D., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

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

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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