

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-180/S-027

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-180\S-027

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:

We acknowledge receipt of your Changes Being Effected (CBE) submission, dated and received on August 15, 2003, for your supplemental new drug application for PROSCAR (finasteride), 5 mg tablets. This submission contains a revised package insert (PI) and patient package insert (PPI) that propose 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.

We have reviewed the labeling that you submitted in accordance with our June 13, 2003 teleconference, and the draft labeling submitted as electronic desk copies on July 18 and 21, 2003. Comparison was also made against final printed labeling (FPL) submitted on May 3, 2001 (SLR-022). This application is 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 enclosed package insert and patient package insert labeling, submitted and received on August 15, 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 027." 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).

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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

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
9/9/03 09:08:28 AM