DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-788/S-002
NDA 20-788/S-010
NDA 20-788/S-011

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

Dear Dr. Fuh:

Please refer to your supplemental new drug applications dated November 9, 1998, received November 10, 1998 for S-002, November 12, 2003, received November 13, 2003 for S-010, and November 20, 2003, received November 21, 2003 for S-011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROPECIA® (finasteride) Tablets, 1 mg.

We acknowledge receipt of your submissions to S-002, S-010, and S-011 dated:

S-002	S-010	S-011
April 20, 2004	May 21, 2004	May 21, 2004
May 21, 2004	August 23, 2004	August 23, 2004
August 23, 2004		

Your submissions dated April 20, 2004 for S-002 and May 21, 2004 for S-010 and S-011 constitute a complete response to our action letters dated December 23, 2004 for S-002 and May 11, 2004 for S-010 and S-011.

These supplemental new drug applications provide labeling changes to the PROPECIA® (finasteride) Tablets, 1 mg as follows:

> Supplement 002 provides labeling revisions to incorporate wording that is consistent with PROSCAR® (finasteride) Tablets, 5mg label, as per the Phase 4 commitment listed in the December 9, 1997 approval letter for NDA 20-788, PROPECIA (finasteride) Tablets, 1 mg.
>
> Supplement 010 and Supplement 011 provide labeling revisions to include wording for male breast cancer adverse events and to reflect inclusion of additional information from the Prostate Cancer Prevention Trial previously incorporated in the PROSCAR® (finasteride) Tablets, 5 mg labeling.

We completed our review of these applications, as amended. These applications are 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 text (text for the package insert and text for the patient package insert) submitted October 20, 2004.

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 purpose, these submissions should be designate "FPL for approved Supplements NDA 20-788/S-002, S-010 and S-011. Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division 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, MD 20857

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 Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan Wilkin, M.D.
Division Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

{See appended electronic signature page}

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Stanka Kukich
10/21/04 04:41:03 PM
Sign off for Dr. Jonathan Wilkin, Division Director