DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-788/S-004
NDA 20-788/S-005
NDA 20-788/S-007

Merck & Company, Inc.
Attention: Michael D. Rozycki, Ph.D.
Associate Director, Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLA-20
West Point, Pennsylvania 19486-0004

Dear Dr. Rozycki:

Please refer to your new supplemental drug applications dated April 1, 1999, received April 2, 1999 (S-004); August 24, 1999 received August 25, 1999 (S-005), and April 9, 2001 received April 10, 2001 (S-007), 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 for S-004, S-005 and S-007:

S-004 Dated:
September 27, 2000
February 28, 2001
May 25, 2001
January 23, 2002
February 25, 2002
April 1, 2002

S-005 Dated:
September 9 and 22, 1999
April 6, 2001
January 23, 2002
February 25, 2002
April 1, 2002

S-007 Dated:
May 17, and 21, 2001
October 23, 2001
December 12, 2001
January 18, 2002
January 29, 2002
February 13, 2002
March 8, 2002
April 1, 2002

These supplemental new drug applications provide for the inclusion of the following into the labeling: 1) adverse events in the ADVERSE REACTION section (S-004), 2) a Geriatric Use subsection under the PRECAUTIONS section (S-005), and 3) the addition of data obtained from a five year extension study into the Clinical Studies subsection (S-007).

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, these applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and text for the patient package insert).

Please 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 ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 20-788/S-004, S-005 and S-007." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

If you have any questions, call Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.
Director
Division of Dermatologic and Dental Drug Products
Office of Drug Evaluation V
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/

Jonathan Wilkin

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