CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20180/S11

CORRESPONDENCE

Robert E. Silverman, M.D., Ph.D.
Director
Regulatory Affairs

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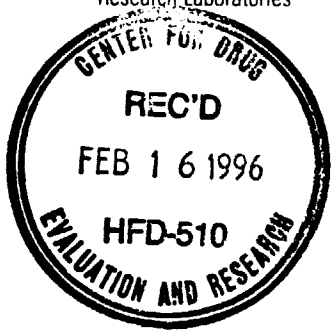
SLR

Merck & Co., Inc.
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2944
215 652 5000

Changes in labelling are acceptable and reflect new preclinical data
9/11/96

February 15, 1996



Solomon Sobel, M.D. - Director
Division of Metabolism and Endocrine Drug Products
HFD-510, Room 14B-04
Office of Drug Evaluation II (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Have pediatric use reviewed
5/3/96

Dear Dr. Sobel:

Supplemental New Drug Application
NDA 20-180: PROSCAR™ (Finasteride)

Pursuant to Section 505(b) of the Food Drug and Cosmetic Act and in accordance with 21 CFR 314.70(b), we submit, for your approval, a supplement to NDA 20-180.

As indicated on the attached Form FDA 356h, the supplemental application provides for changes in Item 4.c.i of the approved New Drug Application for PROSCAR™ Tablets. These include related revisions to the product label in the CLINICAL PHARMACOLOGY, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, and HOW SUPPLIED sections. In addition, the Patient Package Insert has been changed to reflect the proposed label revisions.

This supplemental NDA (sNDA) proposes the revision of the product label and corresponding Patient Product Insert (PPI) to reflect new pre-clinical and clinical information on the potential effect of finasteride exposure from semen in women who are or may be pregnant. The results of these studies allay the previous theoretical safety concerns about semen exposure. Therefore, this sNDA also proposes the removal from the product label and PPI of the specific warning about semen exposure which is no longer warranted.

This supplemental application is organized as a series of sections:

The changes in "How Supplied" section are acceptable.
MJN 9/10/96

Section 1:	Table of Organization and Overview
Section 2:	Draft Annotated Package Circular and Patient Package Insert
Section 3:	Expression of 5 α-Reductase in Rhesus Fetal Tissue
Section 4:	Finasteride-Nonclinical Pharmacology and Toxicology Documentation Reproductive Toxicity
Section 5:	Bioanalytical Reports: Protocol 056 - A Double-Blind, Placebo-Controlled Multicenter Study to Determine the Effects of Finasteride on Semen Production in Male Volunteers

9/24/96

Protocol 065 - A Double-Blind, Placebo-Controlled Study to Investigate the Effects of Finasteride on DHT and Testosterone in Scalp Skin and Sebum
Protocol 012 - A Double-Blind, Placebo-Controlled, Multi-Center Study to Determine the Effects of Finasteride on Semen Production in Male Volunteers

Section 6: Postmarketing Surveillance of PROSCAR™ Exposure During Pregnancy.

In accordance with the Prescription Drug User Fee Act of 1992, a check in the amount of

As required by Section 306(k)(1) of the Generic Drug Enforcement Act [21 U.S.C. 335a (k)(1)], we hereby certify that, in connection with this application, Merck & Co., Inc. did not and will not use in any capacity the services of any person debarred under subsections 306 (a) or (b) of the Act.

We consider the filing of this Supplemental New Drug Application to be a confidential matter, and request the Food and Drug Administration not to make its content, nor any future communications in regard to it, public without first obtaining the written permission of Merck & Co., Inc.

Questions concerning this supplemental application should be directed to Robert E. Silverman, M.D., Ph.D. (610/397-2944) or, in my absence, Bonnie J. Goldmann, M.D. (610/397-2383).

REVIEWS COMPLETED

CSO ACTION:

☐ LETTER ☐ N.A.I.

CSO INITIALS DATE

Sincerely yours,

Robert E. Silverman, M.D., Ph.D.
Director, Regulatory Affairs

Attachments
Federal Express #1

Desk Copy: Dr. Jeri El Hage, HFD-510, Rm. 14B-04, Fedral Express #1
Dr. Jean Fourcroy, HFD-510, Rm. 14B-04, Federal Express #1
Mr. Stephen Trostle, CSO, HFD-510, Rm. 14B-04, Federal Express #1

q/mcs/ltr/284