CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20180/S17

APPROVAL LETTER

NDA 20-180/S-017

DEC 19 1997

Merck Research Laboratories
Attention: Robert E. Silverman, M.D., Ph.D.
Director, Regulatory Affairs
P.O. Box 4
West Point PA 19486

Dear Dr. Silverman:

Please refer to your supplemental new drug application dated April 3, 1997, received April 4, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act and the provisions of 21 CFR 314.70(c) for Proscar (finasteride).

We acknowledge receipt of your submission dated November 21, 1997.

The supplemental application provides for a revision of the bottle labels, carton labels for blister packs, and blister packs to include a warning that reads as follows:

We note that this submission was erroneously submitted as final printed labeling to supplement 011 of this application, instead of as a Changes Being Effected supplement. Therefore, for administrative purposes, we have renumbered this submission as supplement 017.

We have completed the review of this supplemental application, including the submitted draft labeling, 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 draft labeling in the submission dated November 21, 1997. Accordingly, the supplemental application is approved.

The final printed labeling (FPL) must be identical to the draft labeling submitted on November 21, 1997.

Please submit 20 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. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved supplemental NDA 20-180/S-017. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

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, please contact Christina Kish, Project Manager, at (301) 827-4260.

Sincerely,

/S/ 12-17-97

Lisa D. Rarick, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Orig. NDA
HFD-580
HFD-580/MHirsch/HJolson/TRumble
DISTRICT OFFICE
HF-2/Medwatch (with labeling)
HFD-92/DDM-DIAB (with labeling)
HFD-40/DDMAC (with labeling)
HFD-613/OGD (with labeling)
HFI-20/Press Office (with labeling)
HFD-580/CKish/12.12.97/n20180ap.s17
concurrence:LPauls 12.16.97/MHirsch 12.16.97/HJolson 12.17.97

SUPPLEMENT APPROVAL (S/AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20180/S17

ADMINISTRATIVE DOCUMENTS

ORIGINAL

NDA 20-180 **SLR**-011FA

Medical Officer Memorandum

Drug: Proscar® Tablets
Sponsor: Merck Research Laboratories
Submission Date: November 21, 1997
MOR complete date: December 11, 1997

Background:
In this submission by telefacsimile, the sponsor has submitted the revised bottle label proposal for 30 and 100 Tablet Packages and the Carton Labels for Blister Pack 100 Tablet Packages. On the front of the bottle and blister pack labels there will be a bold-faced warning as follows:

Clinical Comment:
The Division agrees that the revised warning adequately addresses the concern that women who are or may potentially be pregnant should not handle broken tablets of Proscar. Therefore, the warning is acceptable as revised.

Recommended regulatory action:
The clinical comment will be conveyed to the sponsor as appropriate.

Mark S. Hirsch, M.D.
Medical Officer
DRUDP
12/16/97
cc: NDA 20-180
HFD-580 Division File
HFD-580/LRarick/HJolson/MHirsch/TRumble/CKish/MRhee

ORIGINAL

NDA 20-180 **SLR**-011FA

Medical Officer Labeling Review

NOV 10

Drug: Proscar® Tablets
Sponsor: Merck Research Laboratories
Submission Date: April 3, 1997
MOR complete date: November 7, 1997

Background:
In this submission, the sponsor includes the bottle label for 30 and 100 Tablet Packages and the Carton Labels for Blister Pack 100 Tablet Packages, to be used in conjunction with package circular # 7819206. On the front of the bottle and blister pack labels there is a bold-faced warning as follows:

Clinical Comment:
The Division recommends that this warning be revised to account for tablets which are less damaged, for example, tablets in which the film coating is merely broken without the tablet actually being "crushed". Therefore, the sponsor should change the bottle and carton label as follows:

Recommended regulatory action:
A regulatory letter should be drafted to convey this recommendation to the sponsor.

/S/

Concur: 1/10/97 /S/

Mark S. Hirsch, M.D.
Medical Officer
DRUDP
cc: NDA 20-180
HFD-580 Division File
HFD-580/LRarick/HJolson/MHirsch/TRumble/CKish/MRhee

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20180/S17

CORRESPONDENCE

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

Merck & Co., Inc.
P.O. Box 4
West Point PA 19486
Fax 610 397 2516
Tel 610 397 2944
215 652 5000

These copies are OFFICIAL FDA Copies
not desk copies.

April 3, 1997

MERCK
Research Laboratories

Lisa D. Rarick, M.D., Division Director
Division of Reproductive and Urologic
Drug Products, HFD-580
Office of Drug Evaluation II (CDER)
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

NDA NO. 20-180 REF. NO.
[illegible] SUPPL FOR 5L2 - SS

REVIEWS COMPLETED
CSO ACTION: ☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

Dear Dr. Rarick:

Final Printed Labeling

Supplemental New Drug Application: NDA 20-180/S-011
PROSCAR™ (Finasteride)

Reference is made to the Supplemental New Drug Application S-011 for PROSCAR™ (Finasteride) submitted on February 15, 1996, to your approval letter dated August 28, 1996, and to the final printed package circular submitted January 14, 1997. This supplemental application provided for the removal from the label of the specific warnings concerning finasteride exposure from semen in women who are or may be pregnant.

Attached for submission as Final Printed Labeling to be used in conjunction with circulars #7819206 and #7819304 for the approved supplement cited above are:

Tab	Attachment
1	Summary of Revisions
2	Bottle Label (30 Tablet Package)
3	Bottle Label (100 Tablet Package)
4	Carton Labels for Blister Pack (100 Tablet Package), Front Wrap-around and Back
5	Blister Pack (100 Tablet Package)

CENTER FOR DRUG
REC'D
APR 04 1997

Lisa D. Rarick, M.D., Division Director
Supplemental New Drug Application: NDA 20-180/S-011
PROSCAR™ (Finasteride)

These changes will become effective on or about April 1, 1997 and will apply to all packages of PROSCAR™ distributed from the Company's manufacturing facilities in West Point , PA.

As required by Section 306(k)(1) of the Generic 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 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, to Bonnie J. Goldmann, M.D. (610/397-2383).

Sincerely yours,

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

Attachments:
Federal Express #1

Desk Copy: Ms. Terry Rumble, Project Manager, HFD-580, Room 17B-45
Federal Express #2

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