CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-180/S-024

Trade Name: Proscar Tablets

Generic Name: finasteride

Sponsor: Merck & Company, Inc

Approval Date: November 26, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-180/S-024

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APPLICATION NUMBER:

NDA 20-180/S-024

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-180 / S-024

MERCK & Co., Inc.
Attention: Michael D. Rozycki, Ph.D.
Associate Director, Regulatory Affairs
Sumneytown Pike
West Point, PA 19486-0004

Dear Dr. Rozycki,

Please refer to your supplemental new drug application dated May24, 2002, received May 29, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROSCAR™ (finasteride 5 mg).

We acknowledge receipt of your submission dated November 22, 2002.

This "Changes Being Effected" supplemental new drug application provides for adding a stability-indicating test method for quantitative estimation of degradants during stability testing for the drug product Proscar.

We completed our review of this supplemental new drug application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Karen Anderson, NP, Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

David T. Lin, Ph.D.
Chemistry Team Leader
@ Division of Reproductive and Urologic Drug Products
(HFD-580)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

David T. Lin
11/26/02 02:37:32 PM
I concur.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-180/S-024

CHEMISTRY REVIEW

CHEMIST REVIEW
OF **Supplement**

1. **ORGANIZATION: HFD 580**
2. **NDA NUMBER: 20180**
3. **SUPPLEMENT NUMBERS/DATES: SCS024**
   Letterdate: 24-MAY-2002
   Stampdate: 29-MAY-2002
4. **AMENDMENTS/REPORTS/DATES:**
   Letterdate: 22-NOV-2002 (faxed)
   Stampdate: 26-Nov-2002
5. **RECEIVED BY CHEMIST: 3-JUNE-2002**

6. **APPLICANT NAME AND ADDRESS: Merck & Co., Inc.**
   Sumneytown Pike
   P.O. Box – 4, BLA-20
   West Point, PA 19486

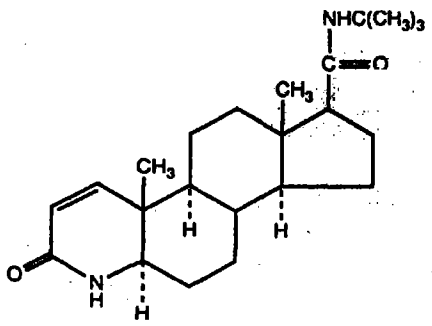
7. **NAME OF DRUG: Proscar™**

8. **NONPROPRIETARY NAME: Finasteride**

9. **CHEMICAL NAME/STRUCTURE:**

   Chemical name: N-(1, 1-dimethylethyl)-3-oxo-4-aza-5α-androst-1-ene-17β-carboxymide

   Structural Formula:



10. **DOSAGE FORM(S): Tablets**

11. **POTENCY: 5 mg**

12. **PHARMACOLOGICAL CATEGORY: Treatment and control of symptomatic benign hyperplaisa (BPH) in men with an enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, reduce the risk of the need for surgery including transurethral resection of the prostate (TURP) and prostatectomy.**

13. **HOW DISPENSED: Oral**

14. **RECORDS & REPORTS CURRENT: Yes**

15. **RELATED IND/NDA/DMF: None**

16. SUPPLEMENT- CHANGES BEING EFFECTED PROVIDES FOR: Adding stability-indicating test method for quantitative estimation of degradants during stability testing for the drug product Proscar.

17. COMMENTS:

The sponsor has included following information to support the CBE supplement.

- Stability-indicating test method (SIM)
- Method validation data for the SIM
- Environmental Assessment-categorical exclusion
- Updated stability protocol.

The information is deemed satisfactory following a t-con with the sponsor dated 21-NOV-2002 to include acceptance criterion for the degradants and commitment to report the degradants above [ ]% and the shelf life acceptance criterion for individual impurities NMT [ ]% and total impurities NMT [ ]% (see chemist's review notes).

18. CONCLUSIONS AND RECOMMENDATIONS:

This CBE-30 supplement may be approved.
Issue Approval Letter

19. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Swapan K. De, Ph.D.		11/26/2002

cc: Original: NDA #20-180
HFD-580/Division File
HFD-580/KingJ
HFD-580/DTLin/SDe
R/D INIT by: David T. Lin, Ph.D.

Filename: nda20-180.scs024

Redacted 3 page(s)

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confidential commercial

information from

Chemistry Review

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/s/

Swapan De
11/26/02 09:17:33 AM
CHEMIST

David T. Lin
11/26/02 12:17:12 PM
CHEMIST
I concur.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-180/S-024

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-180/S-024

CBE-0 SUPPLEMENT

MERCK Research Laboratories
Attention: Michael D. Rozycki, Ph.D.
Associate Director, Regulatory Affairs
Sumneytown Pike
P.o. Box 4 BLA-20
West Point, PA 19486

Dear Dr. Rozycki:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	PROSCAR™ (finasteride)
NDA Number:	20-180
Supplement number:	S-024
Date of supplement:	May 24, 2002
Date of receipt:	May 28, 2002

This supplemental application was submitted as a "Supplement - Changes Being Effected." The appropriateness of reporting the proposed changes as changes being effected is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 28, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service/Courier/Overnight Mail:
Center for Drug Evaluation and Research
Division of Reproductive and Urologic Drug Products, HFD-580
Attention: Division Document Room, 17B20
5600 Fishers Lane
Rockville, Maryland 20857

If you have any question contact me at (301) 827-4260.

Sincerely,

Jennifer Mercier
Regulatory Health Project Manager
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

cpms, rpm, or chem tl signature block

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/s/

Jennifer L. Mercier
5/31/02 10:35:58 AM