CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

NDA 20-180/S-023

Trade Name: Proscar Tablets

Generic Name: finasteride

Sponsor: Merck & Company, Inc

Approval Date: October 28, 2004

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-180/S-023

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APPLICATION NUMBER:

NDA 20-180/S-023

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-180/S-023

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

Dear Dr. Rozycki:

Please refer to your supplemental new drug application dated April 30, 2002, received May 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROSCAR® (finasteride).

This "Changes Being Effected in 30 days" supplemental new drug application provides for a replacement of the current[ ] preparation of the[ ] in the[ ] step of the finasteride process with the use of a[ ].

We have completed the review of this supplemental application, and it is approved.

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 Jennifer Mercier, B.S., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

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

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

/s/

David T. Lin
10/28/02 11:56:08 AM
I concur.

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APPLICATION NUMBER:

NDA 20-180/S-023

CHEMISTRY REVIEW

CHEMIST REVIEW
OF **Supplement**

1. **ORGANIZATION: HFD 580**
2. **NDA NUMBER: 20180**
3. **SUPPLEMENT NUMBERS/DATES: SCS023**
   Letterdate: 30-APR-2002
   Stampdate: 01-MAY-2002
4. **AMENDMENTS/REPORTS/DATES: None**
   Letterdate:
   Stampdate:
5. **RECEIVED BY CHEMIST: 3-MAY-2002**

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

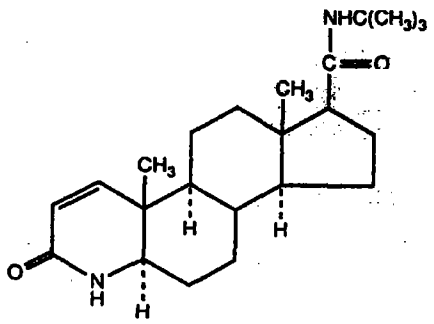
7. **NAME OF DRUG: Proscar™**

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: A replacement of the current[ ] preparation of the [ ] in the [ ] step of the finasteride process with the use of a [ ]

17. COMMENTS:

The sponsor has included a description of the process change due to the proposed change of using [ ] The supplement is deemed satisfactory and may be approved due to the following reasons.

- It is deemed an improvement of the process since [ ] is difficult to control. Furthermore, the sponsor justified the use of [ ] [ ] to reduce the health risk of the operator from [ ] during the operation.
- The sponsor has provided comparable batch analysis data as supportive documentation of the proposed change of [ ] Three batches of finasteride manufactured with [ ] (215-1504500, 215-1504510 and 215-1504520) are compared with three batches of finasteride manufactured with [ ] (215-1504470, 215-1504480 and 215-1504490). The data are closely comparable between the two processes, meet the acceptance criteria and is deemed satisfactory. (see chemistry review notes).
- The sponsor has requested a categorical exclusion from the requirement to prepare an Environmental Assessment under 21 CFR 25.31(a). It is stated that the supplement meets the requirement of categorical exclusion (21 CFR 25.31 (a) because it will not increase the use of the drug. The justification is deemed reasonable.

18. CONCLUSIONS AND RECOMMENDATIONS:

The CBE-0 supplement may be approved.
Issue Approval Letter

19. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Swapan K. De, Ph.D.		10/21/2002

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

Filename: nda20-180.scs023

Redacted 5 page(s)

of trade secret and/or

confidential commercial

information from

Chemistry Review

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/s/

Swapan De
10/22/02 02:08:30 PM
CHEMIST

David T. Lin
10/23/02 07:56:44 AM
CHEMIST
I concur.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-180/S-023

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-180

CBE-0 SUPPLEMENT

Merck Research Laboratories
Attention: Michael 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-023
Date of supplement:	April 30, 2002
Date of receipt:	May 1, 2002

This supplemental application was submitted as a "Supplement - Changes Being Effected." The appropriateness of reporting the proposed change(s) 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 1, 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 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
5/9/02 10:30:01 AM