CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-788

CHEMISTRY REVIEW(S)

DEC 10 1997

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
HFD-540
Review of Chemistry, Manufacturing, and Controls

NDA #: 20-788 CHEM.REVIEW # 1 REVIEW DATE: 10-DEC-1997

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
Original	20-DEC-1996	20-DEC-1996	03-JAN-1997
Amendment/BC	15-JAN-1997	17-JAN-1997	23-JAN-1997
Amendment/BC	07-FEB-1997	10-FEB-1997	
Amendment/BC	07-MAR-1997	10-MAR-1997	24-MAR-1997
Amendment/NC	10-MAR-1997	11-MAR-1997	24-MAR-1997
Amendment/NC	24-APR-1997	25-APR-1997	30-APR-1997
Amendment/BC	06-JUN-1997	09-JUN-1997	17-JUN-1997
Amendment/BL	20-NOV-1997	21-NOV-1997	24-NOV-1997

NAME & ADDRESS OF APPLICANT: Merck and Co., Inc.
Sumneytown Pike
West Point, PA 19486

DRUG PRODUCT NAME

Proprietary:	Propecia™ (proposed)
Nonproprietary/USAN:	Finasteride
Code Names/#'s:	L-652,931
Chemical Type/	Azasteroid/
Therapeutic Class:	4027510 (Hair Growth Agent)

ANDA Suitability Petition/DESI/Patent Status: N/A

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of male pattern baldness.

DOSAGE FORM: Tablet

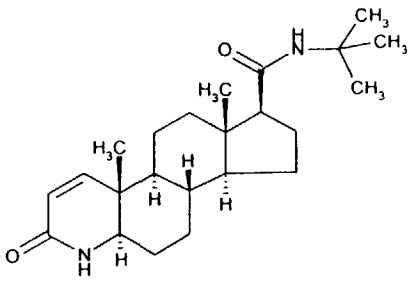
STRENGTHS: 1mg

ROUTE OF ADMINISTRATION: Oral (immediate release)

DISPENSED: __X__ Rx _____ OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:
N-(1,1-dimethyl)-3-oxo-4-aza-5α-androst-1-ene-17β-carboxamide

Molecular Formula: $C_{23}H_{36}N_2O_2$
Molecular Weight: 372.56
CAS Number:
Molecular Structure:



SUPPORTING DOCUMENTS:

DMF

Letter of Authorization dated 18-JUL-1996, signed by E. L. McKinley, Manager of Regulatory Affairs (Vol. 1.2, p. C-70). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 10-JUL-1996, signed by Raymond J. Esce, Q.A. Supervisor (Vol. 1.2, p. C-71). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 11-JUL-1996, signed by Robert P. Fischer, Coordinator of FDA Affairs (Vol. 1.2, p. C-72). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 11-JUL-1996, signed by Robert P. Fischer, Coordinator of FDA Affairs (Vol. 1.2, p. C-73). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 3-JUL-1996, signed by E. L. McKinley, Manager of Regulatory Affairs (Vol. 1.2, p. C-74). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 9-JUL-1996, signed by David J. Mullen, Product Responsibility Sr. Engineer (Vol. 1.2, p. C-75). Responsibility for marketing this item was transferred to

(Vol. 1.2, p. C-76). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 3-JUL-1996, signed by E. L. McKinley, Manager of Regulatory Affairs (Vol. 1.2, p. C-77). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 22-AUG-1995, signed by Matthew L. Rix, Manager, Quality Assurance (Vol. 1.2, p. C-78). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 3-JUL-1996, signed by B. Stultz (Vol. 1.2, p. C-79). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 26-AUG-1996, signed by William R. Schmitt (Vol. 1.2, p. C-80). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 9-SEP-1996, signed by David R. Schoneker, Director of Global Regulatory Affairs (Vol. 1.2, p. C-4). This DMF is acceptable in support of this NDA.

DMF

Letter of Authorization dated 24-JUN-1996, signed by Janice A. Enzinger, Sr. Regulatory Affairs Manager (Vol. 1.2, p. B-5). This DMF has been reviewed in support of this NDA and found to be adequate to support the NDA. An Information Request letter was issued to the DMF holder for several minor inconsistencies in the labeling and specifications for this material. See the accompanying DMF review.

RELATED DOCUMENTS:

NDA 20-180 and IND

Currently active in HFD-510.

IND
Currently active in HFD-540.

DMF

As this DMF is held by the applicant, no Letter of Authorization is necessary. This DMF is acceptable in support of this NDA.

CONSULTS:

The proposed trade name was submitted to the Labeling and Nomenclature Committee (LNC) through Chairman Dan Boring, Ph.D. (HFD-530). The LNC determined unanimously that the proposed trade name was acceptable, as shown in the attached communication dated 23-APR-1997.

REMARKS/COMMENTS:

A recent FDA draft policy has set restrictions on the acceptability of proposed proprietary names for new drug products where the active ingredient of the NDA under review is marketed under another, currently approved, NDA. The proposed trade name "PROPECIA" was submitted and accepted by the LNC prior to the adoption of this policy. While this trade name was found acceptable under the standard at its submission, it may yet be found to be unacceptable in light of this new draft policy.

CONCLUSIONS & RECOMMENDATIONS: **APPROVABLE**

This application is recommended for approval of the chemistry, manufacturing and controls information presented in the application and amendments.

12/10/97

J. S. Hathaway, Ph.D.
Reviewing Chemist

cc: Orig. NDA 20-788
HFD-540/DivisionFile
HFD-540/Chem/JSHathaway
HFD-540/DivDir/JWilkin
HFD-540/MedOffr/HSKo
HFD-540/Pharm/JAvalos
HFD-540/ProjMgr/SKummerer
HFD-540/ChemTeamLdr/WHDeCamp 12/10/97
HFD-830/DivDir/CWChen

filename: C:\WPFILES\NDAS\NDA20788\N20788RW.000

APPROVABLE