CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-788

CHEMISTRY REVIEW(S)
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
Amendment/BC  07-FEB-1997  10-FEB-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/N's: L-652,931
Chemical Type/Therapeutic Class: Azasteroid/(Hair Growth Agent)

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

PHARMACOLOGICAL CATEGORY/INDICATION: Treatment of male pattern baldness.

DOSEAGE FORM: Tablet
STRENGTH: 1mg
ROUTE OF ADMINISTRATION: Oral (immediate release)

DISPENSED: 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: C19H24N2O2
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.
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.

J. E. 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
HFD-830/DivDir/CWChen

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APPROVABLE