

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-834

CHEMISTRY REVIEW(S)

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS

HFD-540

Review of Chemistry, Manufacturing, and Controls

SUBMISSION/TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
ORIGINAL	28-FEB-1997	28-FEB-1997	05-MAR-1997
AMENDMENT/BC	22-APR-1997	23-APR-1997	25-APR-1997
AMENDMENT/BC	22-JUL-1997	24-JUL-1997	29-JUL-1997
AMENDMENT/BC	23-JUL-1997	24-JUL-1997	29-JUL-1997
AMENDMENT/BC	04-AUG-1997	05-AUG-1997	08-AUG-1997
AMENDMENT/BC	04-AUG-1997	05-AUG-1997	08-AUG-1997
AMENDMENT/BC	29-OCT-1997	30-OCT-1997	30-OCT-1997
AMENDMENT/BC	03-NOV-1997	04-NOV-1997	05-NOV-1997
IND 13,267/N-154	26-DEC-1996	27-DEC-1996	07-JAN-1997

NAME & ADDRESS OF APPLICANT: Pharmacia and Upjohn Company
7031-298-112
7000 Portage Road
Kalamazoo, MI 49001

DRUG PRODUCT NAME

Proprietary:	ROGAINE Extra Strength for Men
Nonproprietary/USAN:	Minoxidil
Code Names/#'s:	U-10,858
Chemical Type/	Triaminopyrimidine N-oxide
Therapeutic Class:	3 S

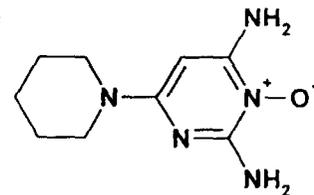
ANDA Suitability Petition/DESI/Patent Status: N/A

PHARMACOLOGICAL CATEGORY/INDICATION: For treatment of androgenic alopecia.

DOSAGE FORM: Solution
STRENGTHS: 5%
ROUTE OF ADMINISTRATION: Topical
DISPENSED: _____ Rx X OTC

CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOL.WT:

6-(1-Piperidinyl)-2,4-pyrimidinediamine 3-oxide



Molecular Formula: C₁₁H₁₇N₃O
Molecular Weight: 209.25
Melting Range: 240°C (dec)
CAS Number: [38304-91-5]

PATENT STATUS**A. Patent Information**

Below are listed all patents known to the applicant that claim the drug or a method of using the drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, sale, or use of the drug.

1. U.S. Patent No.: 4,113,619
Issue Date:
Expiration Date: 13-FEB-1996
Patent Owner: Upjohn
Claims For: Compound

2. U.S. Patent No.: 4,843,086
Issue Date:
Expiration Date: 13-FEB-1996
Patent Owner: Upjohn
Claims For: Method of treatment for alopecia with
minoxidil and solvent

A period of three years of market exclusivity has been requested by the applicant (Vol. 1.1).

SUPPORTING DOCUMENTS:

DMF

~~DMF~~

DMF

DMF

DMF

DMF

RELATED DOCUMENTS:

NDA 18-154, LONITEN® Tablets, Pharmacia and Upjohn.

NDA 19-501, ROGAINE® 2% Topical Solution, Pharmacia and Upjohn.

Letter from
for

regarding specifications

material.

No DMF has been submitted for this

CONSULTS:

Trade name acceptability consultation was sent to the FDA Labeling and Nomenclature Committee; the decision of the LNC was that the proposed Trade name "ROGAINE Extra Strength for Men" is acceptable. A copy of their finding is attached.

CONCLUSIONS & RECOMMENDATIONS:

APPROVED

This application, after review of the chemistry, manufacturing and controls information, is approvable. The following changes in the labeling should be made by the applicant before approval:

The following is not a condition of approvability, but is a request strongly supported by the reviewer:

4. The revisions above should also be applied to the packaging of Rogaine 2% Topical Minoxidil Solution for Men, and Rogaine 2% Topical Minoxidil Solution for Women at the next printing of these materials.

11/5/97
J. S. Hathaway, Ph.D.
Reviewing Chemist, DNDC III

Original to NDA 20-834

cc: NDA 19-501
IND 13,267
HFD-540/DivisionFile
HFD-540/DivDir/JKWilkin
HFD-540/Chem/JSHathaway
HFD-540/MedOffr/PHeune
HFD-540/Pharm/JAvalos
HFD-540/Stat/SFarr
HFD-160/Micro/BUratani
HFD-880/Biopharm/AEITahtawy
HFD-540/ProjMgr/MJKozmaFornaro
HFD-540/ChemTeamLdr/WHDeCamp
HFD-560/MedOffr/SAurecchia

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APPROVABLE