CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-834

ADMINISTRATIVE DOCUMENTS

PEDIATRIC PAGE

(Complete for all original applications and all efficacy supplements)

NDA/PLA # 20834 Supplement # _____ Circle one: SE1 SE2 SE3 SE4 SE5 SE6

HFD 540 Trade (generic) name/dosage form: Rogaine Extra Strength for Men (Minoxidil) 5%/6 Action: (AP) AE NA

Applicant Pharmacia Upjohn Therapeutic Class HAIR Regrowth Stimulant

Indication(s) previously approved none for this strength

Pediatric labeling of approved indication(s) is adequate ___ inadequate ___ NA

Indication in this application HAIR Regrowth Treatment for Men

(For supplements, answer the following questions in relation to the proposed indication.)

___ 1. **PEDIATRIC LABELING IS ADEQUATE.** Appropriate information has been submitted in this or previous applications and has been adequately summarized in the labeling to permit satisfactory labeling for all pediatric subgroups. Further information is not required.

___ 2. **PEDIATRIC STUDIES ARE NEEDED.** There is potential for use in children, and further information is required to permit adequate labeling for this use.

___ a. A new dosing formation is needed, and applicant has agreed to provide the appropriate formulation.

___ b. The applicant has committed to doing such studies as will be required.
- ___ (1) Studies are ongoing.
- ___ (2) Protocols were submitted and approved.
- ___ (3) Protocols were submitted and are under review.
- ___ (4) If no protocol has been submitted, explain the status of discussions on the back of this form.

___ c. If the sponsor is not willing to do pediatric studies, attach copies of FDA's written request that such studies be done and of the sponsor's written response to that request.

X 3. **PEDIATRIC STUDIES ARE NOT NEEDED.** The drug/biologic product has little potential for use in children. Explain, on the back of this form, why pediatric studies are not needed. For use by men 18 years of age and greater

___ 4. **EXPLAIN.** If none of the above apply, explain, as necessary, on the back of this form.

EXPLAIN, AS NECESSARY, ANY OF THE FOREGOING ITEMS ON THE BACK OF THIS FORM.

11/12/97 _____ 11/14/97

Signature of Preparer and Title (PM, CSO, MO, other) Date

cc: Orig NDA/PLA # 20834
HFD 540 /Div File
NDA/PLA Action Package
HFD-510/GTroendle (plus, for CDER APs and AEs, copy of action letter and labeling)

NOTE: A new Pediatric Page must be completed at the time of each action even though one was prepared at the time of the last action.

5/95

Androgenetic alopecia
is rare in pediatric
patients,

11/14/97

DEBARMENT CERTIFICATION FOR 5% MINOXIDIL TOPICAL SOLUTION

Pursuant to section 306(k)(1) of the Federal Food, Drug and Cosmetic Act, the applicant certifies that, to the best of its knowledge and belief, the applicant did not and will not use in any capacity the services of any person listed pursuant to section 306(e) as debarred under subsections 306(a) or (b) of the Act in connection with this application.

January 24, 1997

Ed L. Patt
Manager
Regulatory Compliance

Date

NDA 20-834
5% Minoxidil Topical Solution

XIII. PATENT INFORMATION

PATENT CERTIFICATION

1.	Active Ingredient	Minoxidil
2.	Strength(s)	5%
3.	Trade Name	To be determined
4.	a. Dosage Form	Solution
	b. Route of Administration	Topical
5.	Applicant Firm Name	Pharmacia & Upjohn Company
6.	NDA Number	20-834
7.	NDA Approval Date	To be determined
8.	Exclusivity - Date first ANDA could be approved and length of exclusivity period	Three (3) years after date of NDA approval.
9.	Applicable patent numbers and expiration date of each	None

This is to certify that the above information is correct to the best of my knowledge.

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

Consult #897 (HFD-540)

ROGAINE EXTRA STRENGTH FOR MEN minoxidil 5% topical solution

ROGAINE is an established trademark for these products and was not evaluated by the Committee. The "EXTRA STRENGTH FOR MEN" was questioned to find out if women may use this product also. The reviewing division assured the LNC that the product was only approvable for men and would be prominently labeled as such. Therefore, the Committee finds no misleading aspects in the proposed name.

The Committee has no reason to find the proposed proprietary name unacceptable.

11/7/97, Chair
CDER Labeling and Nomenclature Committee

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 2, 1996

Ley Smith, President
Kalamazoo Pharma Products Center
Pharmacia & Upjohn
7000 Portage Road
Kalamazoo, MI 49001-0199

Regarding:
NDA Rogaine-5 Topical Solution

Dear Mr. Smith:

This letter is written to advise you that Detroit District has recommended to our Center for Drug Evaluation and Research that NDA be approved. We have made this decision based upon the June 4-6, 1996 inspection of your plant which concentrated upon the manufacturing of the referenced product.

Our Center for Drug Evaluation and Research will make their evaluation and notify your firm accordingly.

Sincerely yours,

Brenda J. Holman
District Director

REGULATORY AFFAIRS
JUL 23 1996
PPC U.S.

RECEIVED
JUL 08 1996
USS

FORWARD PLANNING MEETING SUMMARY

DATE: 4/14/97
PARTICIPANTS FROM FDA:
HFD-540:
Jonathan Wilkin, M.D., Division Director
Janet Higgins, M.S., Chemist (for Steve Hathaway)
Javier Avalos, Ph.D, Pharmacologist/Toxicologist
Robin Anderson, R.N., M.B.A., Project Manager
Mary Jean Kozma-Fornaro, R.N, M.S., Supervisory Project Manager
HFD-725:
R. Srinivasan, Ph.D, Supervisor, Biostatistics
Shala Farr, Ph.D, Biostatistican
HFD-880:
Dennis Bashaw, Ph.D, Biopharmaceutical Team Leader
HFD-560:
Linda Katz, M.D., Deputy Clinical Director
Steve Aurecchia, M.D., Medical Reviewer
Nahid Mokhtari-Rejali, Ph.D, Chemist
Rosemary Cook, M.B A., Supervisory Project Manager
Carol Doyle, Project Manager
HFD-40:
Karen Lechter, Social Science Analyst

SUBJECT:**Rogaine Extra Strength for Men (minoxidil solution, 5%) Topical Solution, 5%, NDA 20-834**

OBJECTIVE: To determine the fileability of NDA 20-834

The meeting was convened to determine the adequacy of NDA 20-834 for filing. All sections of the New Drug Application (NDA) were evaluated in terms of the general content and format requirements. The application was deemed fileable, pending the receipt of statements from the applicant concerning (1) the facilities are ready for inspection and (2) clarifying the release of environmental assessment information by FOI. Applicant was contacted by phone immediately after the meeting and agreed to submit these statements to the NDA ASAP.

Robin Anderson, Project Manager, HFD-540

Attachments (Checklists)

cc:
NDA 20-834
HFD-540/Division File
HFD-540/Wilkin
HFD-540/Huene
HFD-540/DeCamp
HFD-540/Hathaway
HFD-540/Jacobs
HFD-540/Avalos
HFD-540/Kozma-Fornaro 5/12/97
HFD-540/Anderson
HFD-725/Srinivasan
HFD-725/Farr
HFD-880/Bashaw
HFD-40/Lechter
HFD-560/Bowen
HFD-560/Katz
HFD-560/Aurecchia
HFD-560/Mokhtari-Rejali
HFD-560/Cook
HFD-560/Doyle

FORWARD PLANNING MEETING CHECKLIST
April 14,1997
NDA 20-834

Rogaine Extra Strength For Men (minoxidil topical solution, 5%) Topical Solution, 5%
androgenetic alopecia
Pharmacia and Upjohn
Type 3S
Filing Date: 4/29/97
User Fee Date: 2/2/8/98
Regulatory Due Date: 8/27/97 (review promised by this date)
Target date: 7/97

FILEABILITY:
On initial overview of the NDA application:

PROJECT MANAGEMENT:
(1) Do any of the following apply to this application (i.e., if YES , the application MUST BE REFUSED TO FILE under 314.101 (e) and there is no filing over protest):

(a) Is the drug product already covered by an approved application?
NO.

(b) Does the submission purport to be an abbreviated application under 314.55; however the drug product is not one for which FDA has made a finding that an abbreviated application is acceptable under 314.55(b)?
NO.

c) Is the drug product subject to licensing by FDA under the Public Service Act and Subchapter F of Chapter I of Title 21 of the CFR?
NO.

(2) Do any of the following apply to this application (i.e., if NO, the application MAY BE REFUSED TO FILE under 314.101(d) and there is the potential for filing over protest):

(a) Does the application contain a completed application form as required under 314.50 or 314.55?
YES.

(b) On its face, does the application contain the sections of an application required by regulation and Center guidelines?
- Clinical
- Biopharm
- Chemistry
- Pharm/Tox
- Statistics

YES.

C) Has the applicant submitted a complete environmental assessment which addresses each of the items specified in the applicable format under 25.31 or has the applicant submitted evidence to establish that the product is under 25.24 of the CFR?
YES, in Vol. 1.4 and 1.5

(d) On its face, is the NDA formatted in compliance with Center guidelines including integrated efficacy and safety summaries?
YES. Integrated efficacy and safety summaries are located in vol. 1.2.

(e) Is the NDA indexed and paginated?
YES.

(f) On its face, is the NDA legible?
YES.

(g) Has the applicant submitted all required copies of the submission and various sections of the submission?
YES.

(h) Has the sponsor submitted all special studies/data requested by the Division during pre-submission discussions with the sponsor?
YES, as of 4/11/97.

(I) Does the application contain a statement that all nonclinical laboratory studies were conducted in compliance with the requirements set forth in Part 58 or a statement why a study was not conducted in compliance with those requirements?
YES, located in individual study reports.

(j) If required, has the applicant submitted carcinogenicity studies?
YES, in vol. 1.6.

(k) On its face, does the application contain at least two adequate and well-controlled clinical trials?
YES, pivotal studies are located in volume 1.2, pg. 2/1/138: M/7410/0285, M/7410/0286, M/7415/0001 and M/7415/0009. All studies test Minoxidil solution 5% vs. Minoxidil 2% vs. Placebo. All studies conducted in the U. S.

(l) Does the application contain a statement that all clinical trials were conducted in accord with the IRB/Declaration of Helsinki provisions of the CFR?
YES, located in vol. 1.88, pg. 8/8/2

(m) Have all articles/study reports been submitted whether in English or translated into English?
YES.

(n) Has the applicant submitted draft labeling in compliance with 210.56 and 210.57 of the CFR?
YES, copy of label provided to all reviewers.

(o) Has the applicant submitted the required FRAUD POLICY notice?
YES, see debarment statement located in vol. 1.2.

(p) Has the applicant submitted copies of all package inserts (or their equivalent) from all countries in which this product has been previously approved for marketing? Have all non-English package inserts been translated?
Yes, foreign approval/marketing history is located in vol. 1.2, pg. 2/1/39. A side-by-side comparison of the approved topical Minoxidil solution 2% to the proposed Minoxidil solution 5% is located in vol. 1.2, pg. 2/1/1.

(q) Has the applicant stated that the integrated summary of safety includes all safety data for this product of which they are aware from all sources, domestic and foreign? What is the cut-off date for the preparation of the ISS?
YES, cut off date listed as 3/31/95.

(r) If this is a CANDA submission, has the applicant submitted a statement to the archival NDA that the text, tables, and data in the CANDA and the archival hard copy NDA are identical? If they are not identical, is there a letter to the archival NDA that specifies distinctly ALL of the differences in the two submissions?
N/A

(3) From a project management perspective, is this NDA fileable? If "no". please state on the reverse why it is not.
YES.

4/11/97
Project Manager

4/11/97
Supervisory Project Manager

Steve Hathaway

NDA FORWARD PLANNING MEETING CHECKLIST

FILEABILITY: NDA 20-834, ROGAINE® Extra Strength for Men
(5% minoxidil topical solution)

On initial overview of the NDA application:		YES	NO
CHEMISTRY, MANUFACTURING AND CONTROLS:			
(1)	On its face, is the CMC section of the NDA organized in a manner to allow substantive review to begin?	-X-	
(2)	Is the CMC section of the NDA indexed and paginated in a manner to allow substantive review to begin?	-X-	
(3)	On its face, is the CMC section of the NDA legible so that substantive review can begin?	-X-	
(4)	Are all the facilities (manufacturing, packaging, testing, sterilization, etc.) appropriately delineated with full addresses?	-X-	
(5)	Has the applicant provided a statement certifying that all facilities listed in the application are currently ready for inspection?		-X-
(6)	Has the applicant submitted a complete environmental impact assessment?	-X-*	
(7)	Has the applicant developed appropriate controls assessment procedures that are currently ready for FDA verification?	-X-	
(8)	For an antibiotic, has the applicant submitted an appropriate validation package and committed to the readiness of exhibit samples?		N/A
(9)	Has the applicant submitted all special studies/data requested by the Division during pre-submission discussions with the sponsor?	-X-	
(10)	Has the applicant submitted draft labeling consistent with 21 CFR 201.56 and 201.57, current Division labeling policies, and the design of the development package?	-X-	
(11)	Has the applicant submitted stability data to support and justify the proposed expiry?	-X-	
(12)	From a manufacturing and controls perspective, is this NDA fileable? If "No," please state on reverse why it is not.	-X-	

Reviewing Chemist 4/9/97

Supervisory Chemist 4/9/97 for

* Company should submit statement clarifying the release of EA information by FOI. They should list pag #s in EA.

Division of Dermatologic and Dental Drug Products (HFD-540)
Pharmacology/Toxicology Forward Planning Meeting

NDA Number: 20-834 **Date:** April 14, 1997
Drug Name: Minoxidil (5%) **Reviewer:** Javier Avalos
(Rogaine)
CAS Number: 38304-91-5
Drug Type: New Concentration (i.e. NME, new formulation, new indication)
Drug Class: Anti-androgenic
Indication: For the treatment of androgenic alopecia
Route of Administration: Topical
Date CDER Received: March 3, 1997
~~**User Fee Date:**~~ ~~**March 3, 1998**~~ AUGUST 17, 1997
Expected Date of Draft Review: May 20, 1997

Sponsor: Pharmacia & UpJohn Company
700 Portage Road
Kalamazoo, Michigan 49001-0199
(616) 833-5612

Fileability:

On initial overview of the NDA application:	YES	NO
(1) On its face, is the pharmacology/toxicology section of the NDA organized in a manner to allow substantive review to begin? Comments?	X	___
(2) Is the pharm/tox section of the NDA indexed and paginated in a manner to allow substantive review to begin?	X	___
(3) On its face, is the pharm/tox section of the NDA legible so that substantive review can begin?	X	___
(4) Are all required (*) and requested IND studies completed and submitted in this NDA (carcinogenicity, mutagenicity, teratogenicity*, effects on fertility*, juvenile studies, acute studies*, chronic studies*, maximum tolerated dosage determination, dermal irritancy, ocular irritancy, photocarcinogenicity, animal pharmacokinetic studies, etc)? **Comments?**	X	___

(5) If the formulation to be marketed is different from the formulation used in the toxicology studies, has the Sponsor made an appropriate effort to either repeat the studies using the to-be-marketed product or explained why such repetition should not be required? X ___
Comments?

(6) Are the proposed labeling sections relative to pharm/tox appropriate (including human dose multiples expressed in either mg/m^2 or comparative serum/plasma levels) and in accordance with 201.57? ___ X
Comments? The label is an OTC label.

(7) Has the Sponsor submitted all special studies/data requested by the Division during pre-submission discussions with the Sponsor? X ___
Comments?

(8) On its face, does the route of administration used in the animal studies appear to be the same as the intended human exposure route? If not, has the Sponsor submitted a rationale to justify the alternative route? X ___

(9) Has the Sponsor submitted a statement(s) that all of the pivotal pharm/tox studies have been performed in accordance with the GLP regulations (21 CFR 58) or an explanation for any significant deviations? X ___
Comments?

(10) Has the Sponsor submitted the data from the nonclinical carcinogenicity studies, in the STUDIES electronic format, for the review by Biometrics? — ___ X
Comments?

These studies were submitted in the withdrawn NDA 20-492.

(11) Has the Sponsor submitted a statement(s) that the pharm/tox studies have been performed using acceptable, state-of-the-art protocols which also reflect agency animal welfare concerns? X ___
Comments?

(12) From a pharmacology perspective, is this NDA fileable? If "no", please state below why it is not. X ___

(13) If the NDA is fileable, are there any issues that need to be conveyed to Sponsor? If so, specify: ___ X

(14) Issues that should not be conveyed to the Sponsor:

4/14/97

Reviewing Pharmacologist/Toxicologist

4/14/97

Pharmacology/Toxicology Team Leader

OTC

45 DAY MEETING CHECKLIST

FILEABILITY:

On initial overview of the NDA application:	YES	NO

CLINICAL:

(1)	On its face, is the clinical section of the NDA organized in a manner to allow substantive review to begin?	Y
(2)	Is the clinical section of the NDA indexed and paginated in a manner to allow substantive review to begin?	Y
(3)	On its face, is the clinical section of the NDA legible so that substantive review can begin?	Y
(4)	If needed, has the sponsor made an appropriate attempt to determine the most appropriate dosage and schedule for this product (*i.e.*, appropriately designed dose-ranging studies)?	Y
(5)	On its face, do there appear to be the requisite number of adequate and well-controlled studies in the application?	Y
(6)	Are the pivotal efficacy studies of appropriate design to meet basic requirements for approvability of this product based on proposed draft labeling?	Y
(6)	Are all data sets for pivotal efficacy studies complete for all indications ~~(infections)~~ requested?	Y
(7)	Do all pivotal efficacy studies appear to be adequate and well-controlled within current divisional policies (or to the extent agreed to previously with the applicant by the Division) for approvability of this product based on proposed draft labeling?	Y
(8)	Has the applicant submitted line listings in a format to allow reasonable review of the patient data? Has the applicant submitted line listings in the format agreed to previously by the Division?	Y

(9) Has the application submitted a rationale for assuming the applicability of foreign data (disease specific microbiologic specific) in the submission to the US population? N/A

(10) Has the applicant submitted all additional required case record forms (beyond deaths and drop-outs) previously requested by the Division? (Y)

(11) Has the applicant presented the safety data in a manner consistent with Center guidelines and/or in a manner previously agreed to by the Division? (Y)

(12) Has the applicant presented a safety assessment based on all current world-wide knowledge regarding this product? (Y)

(13) Has the applicant submitted draft labeling consistent with 201.56 and 201.57, current divisional policies, and the design of the development package? N/A

(14) Has the applicant submitted all special studies/data requested by the Division during pre-submission discussions with the sponsor? (Y)

(15) From a clinical perspective, is this NDA fileable? If "no", please state below why it is not. (Y)

If certain claims are not filable, please state which claims they are and why they are not filable.

2/14/97

Reviewing Medical Officer

2/14/97

Supervisory Medical Officer

FORWARD PLANNING/FILEABILITY MEETING

NDA 20-834
Rogaine 5% Topical Solution for Men (Minoxidil Solution, 5%)
Hair Regrowth
Phamacia & Upjohn Company
Type: 3S

Filing Date:	**April 29, 1997**
User Fee Date:	**February 28, 1998**
Regulatory Due Date:	**August 27, 1997**
Target Date:	**July, 1997**

FILEABILITY

On initial overview of the NDA application:

	YES	NO

PROJECT MANAGEMENT:

(1) Do any of the following apply to this application (i.e., if YES, the application MUST BE REFUSED TO FILE under 314.100(e) and there is no filing over protest):

(a) Is the drug product already covered by an approved application?		NO
(a) Does the submission purport to be an abbreviated application under 314.55; however the drug product is not one for which FDA has made a finding that an abbreviated application is acceptable under 314.55(b)?		NO
(b) Is the drug product subject to licensing by FDA under the Public Service Act and Subchapter F of Chapter I of Title 21 of the CFR?		NO

(2) Do any of the following apply to this application (i.e., if NO, the application MAY BE REFUSED TO FILE under 314.100(d) and there is the potential for filing over protest):

(a) Does the application contain a completed application form as required under 314.50 or 314.55?	YES	
(b) On its face, does the application contain the sections of an application required by regulation and Center guidelines?	YES	
(c) Has the applicant submitted a complete environmental assessment which addresses each of the items specified in the applicable format under 25.31or has the applicant submitted evidence to establish that the product is subject to categorical exclusion under 25.24 of the CFR?	YES	

(d) On its face, is the NDA formatted in compliance with Center guidelines including integrated efficacy and safety summaries?	YES
(e) Is the NDA indexed and paginated?	YES
(f) On its face, is the NDA legible?	YES
(g) Has the applicant submitted all required copies of the submission and various sections of the submission?	YES
(h) Has the sponsor submitted all special studies/data requested by the Division during Pre-submission discussions with the sponsor?	YES
(i) Does the application contain a statement that all non-clinical laboratory studies was conducted in compliance with the requirements set forth in Part 58 or a statement why a study was not conducted in compliance with those requirements?	YES
(j) If required, has the applicant submitted carcinogenicity studies?	YES
(k) On its face, does the application contain at least two adequate and well-controlled clinical trials? ***Protocol M/7415/0001*** *"Efficacy and Safety Study of 5% TMS vs TMS and PBO"* ***Protocol M/7410/0285*** *"Efficacy and Safety Study of 5% TMS vs 2% TMS and PBO"*	YES
(l) Does the application contain a statement that all clinical trials were conducted in accord with the IRB/Declaration of Helsinki provisions of the CFR?	YES
(m) Have all articles/study reports been submitted either in English or translated into English?	YES
(n) Has the applicant submitted draft labeling in compliance with 210.56 and 210.57 of the CFR?	YES
(o) Has the applicant submitted the required FRAUD POLICY notice?	YES
(p) Has the applicant submitted copies of all package inserts (or their equivalent) from all countries In which this product has been previously approved for marketing? Have all non-English package inserts been translated?	YES

(r) If this is a CANDA submission, has the applicant submitted a statement to the archival NDA that the text, tables, and data in the CANDA and the archival hardcopy NDA are identical? If they are not identical, is there a letter to the archival NDA that specifies distinctly ALL of the differences in the two submissions? N/A

(3) From a project management perspective, is this NDA fileable? If "no", please state on reverse why it is not. YES

Carol Doyle
Project Manager
Division of OTC Drug Products (HFD-560)

4/15/97
Date

Rosemary Cook
Supervisory Project Manager
Division of OTC Drug Products (HFD-560)

4/16/97
Date

cc
Orig NDA 20-834
HFD-560
File
HFD-560/M. Wright

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20-834

CORRESPONDENCE

Received 11/13/97

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs
Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

November 13, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 013

RE: **NDA 20-834**
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

With reference to the above product, NDA 20-834, ROGAINE® Extra Strength for Men and a recent discussion concerning the proposed labeling, we are submitting the revised artwork incorporating the FDA's suggested changes. Enclosed are 15 copies of the artwork for the carton and the cover page of the consumer booklet, they contain the only changes. Our understanding is that the consumer booklet change will occur with the second printing.

Final printed labeling prepared using this artwork will be submitted as soon as possible for all packaging components.

Please contact me at (616) 833-0671 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Carl M. DeFulio for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

1 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Millie Wright, Division of OTC Drug Evaluation (HFD 560)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: 12/31/95
See OMB Statement on Page 3.

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314)*.

NAME OF APPLICANT
Pharmacia & Upjohn Company

DATE OF SUBMISSION
11/13/97

TELEPHONE NO. *(Include Area Code)*
(616) 833-0671

ADDRESS *(Number, Street, City, State and Zip Code)*
7000 Portage Road 9032-227-369
Kalamazoo, Michigan 49001

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued)
20-834

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(if any)*
minoxidil	5% Minoxidil Topical Solution

CODE NAME *(if any)*	CHEMICAL NAME
	2,4-pyrimidinediamine, 6-(1-piperidinyl), 3 oxide

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
solution	topical	5%

PROPOSED INDICATIONS FOR USE

Androgenic alopecia

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

IND

NDA 18-154 LONITEN® Tablets
NDA 19-501 ROGAINE® Topical Solution

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☑ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION

☐ ORIGINAL APPLICATION ☐ RESUBMISSION ☐ GENERAL CORRESPONDENCE

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

CONTENTS OF APPLICATION

s application contains the following items: *(Check all that apply)*

1.	Index
2.	Summary (21 CFR 314.50 (c))
3.	Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))
4. a.	Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)
b.	Methods Validation Package (21 CFR 314.50 (e) (2) (i))
c.	Labeling (21 CFR 314.50 (e) (2) (ii))
i.	draft labeling *(4 copies)*
ii.	final printed labeling (12 copies)
5.	Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))
6.	Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))
7.	Microbiology section (21 CFR 314.50 (d) (4))
8.	Clinical data section (21 CFR 314.50 (d) (5))
9.	Safety update report (21 CFR 314.50 (d) (5) (vi) (b))
10.	Statistical section (21 CFR 314.50 (d) (6))
11.	Case report tabulations (21 CFR 314.50 (f) (1))
12.	Case reports forms (21 CFR 314.50 (f) (1))
13.	Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))
15.	OTHER *(Specify)*

gree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, rnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I ree to comply with all laws and regulations that apply to approved applications, including the following:

1. **Good manufacturing practice regulations in 21 CFR 210 and 211.**
2. **Labeling regulations in 21 CFR 201.**
3. **In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.**
4. **Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.**
5. **Regulations on reports in 21 CFR 314.80 and 314.81.**
6. **Local, state and Federal environmental impact laws.**

this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act I agree not to market the oduct until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
aymond E. Dann, Ph.D., Director onsumer Healthcare, OTC Regulatory Affairs	Carl M DeFulio for	11/13/97

ADDRESS *(Street, City, State, Zip Code)*	TELEPHONE NO. *(Include Area Code)*
7000 Portage Road Kalamazoo, Michigan 49001	(616) 833-0671

WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

FDA [illegible]

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs
Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

October 29, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 011

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

With reference to the above product, NDA 20-834, ROGAINE® Extra Strength for Men, and the teleconference held on October 24, 1997 with Drs. Weintraub, Bowen and Aurecchia concerning the proposed labeling, we are submitting 15 copies of the revised labeling artwork incorporating the FDA's suggested changes. We have also incorporated a number of very minor editorial changes involving grammar and spelling.

Final printed labeling prepared using this artwork will be submitted as soon as possible for all packaging components.

Please contact me at (616) 833-0671 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Carl m. DeJulio for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

1 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Millie Wright, Division of OTC Drug Evaluation (HFD 560)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: 12/31/95
See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314)*.

NAME OF APPLICANT	DATE OF SUBMISSION
Pharmacia & Upjohn Company	10/29/97
ADDRESS *(Number, Street, City, State and Zip Code)* 7000 Portage Road 9032-227-369, Kalamazoo, Michigan 49001	TELEPHONE NO. *(Include Area Code)* (616) 833-0671
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued) 20-834

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(if any)*
minoxidil	5% Minoxidil Topical Solution

CODE NAME *(if any)*	CHEMICAL NAME
	2,4-pyrimidinediamine, 6-(1-piperidinyl), 3 oxide

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
solution	topical	5%

PROPOSED INDICATIONS FOR USE

Androgenic alopecia

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

IND

NDA 18-154 LONITEN® Tablets
NDA 19-501 ROGAINE® Topical Solution

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☑ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION

☐ ORIGINAL APPLICATION ☐ RESUBMISSION ☐ GENERAL CORRESPONDENCE

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

CONTENTS OF APPLICATION

This application contains the following items: *(Check all that apply)*

	1. Index
	2. Summary (21 CFR 314.50 (c))
	3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))
	4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)
	b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))
[redacted]	c. Labeling (21 CFR 314.50 (e) (2) (ii))
	i. draft labeling *(4 copies)*
	ii. final printed labeling (12 copies)
	5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))
	6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))
	7. Microbiology section (21 CFR 314.50 (d) (4))
	8. Clinical data section (21 CFR 314.50 (d) (5))
	9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))
	10. Statistical section (21 CFR 314.50 (d) (6))
	11. Case report tabulations (21 CFR 314.50 (f) (1))
	12. Case reports forms (21 CFR 314.50 (f) (1))
	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))
	15. OTHER *(Specify)*

I agree to update this application with new safety information about the drug that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit these safety update reports as follows: (1) 4 months after the initial submission, (2) following receipt of an approvable letter and (3) at other times as requested by FDA. If this application is approved, I agree to comply with all laws and regulations that apply to approved applications, including the following:

1. **Good manufacturing practice regulations in 21 CFR 210 and 211.**
2. **Labeling regulations in 21 CFR 201.**
3. **In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.**
4. **Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.**
5. **Regulations on reports in 21 CFR 314.80 and 314.81.**
6. **Local, state and Federal envirohmental impact laws.**

If this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

NAME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
Raymond E. Dann, Ph.D., Director Consumer Healthcare, OTC Regulatory Affairs	Carl M. DeFelice for RED.	10/29/97

ADDRESS *(Street, City, State, Zip Code)*	TELEPHONE NO. *(Include Area Code)*
7000 Portage Road Kalamazoo, Michigan 49001	(616) 833-0671

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

August 4, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 009

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting a revised draft consumer booklet (Attachment 1) for ROGAINE® Extra Strength for Men for the Agency's consideration. We have tried to match this booklet's information with the corresponding sections of the proposed draft carton label, submitted in amendment 006 on July 23, 1997. For your reference, we have also attached the previous consumer booklet version (Attachment 2), which was provided to the NDAC in the recent briefing document, as well as submitted in NDA 20-834 on February 28, 1997.

A point-by-point comparison of the current Draft NDA booklet and the revised draft booklet is provided in Table 1. A diskette containing a Word Perfect text file of the proposed draft consumer booklet is enclosed in two desk copies (only) provided to Mary Jean Kosma-Fornaro.

As with amendment 006, we propose to meet with the Agency as soon as possible to discuss these and any other labeling issues in order to expedite the process.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

E. C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

cc: 12 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: 12/31/95
See OMB Statement on Page 3.

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	**NDA/ANDA NO. ASS.**

NOTE: No application may be filed unless a complete application form has been received *(21 CFR Part 314).*

NAME OF APPLICANT
Pharmacia & Upjohn Company

DATE OF SUBMISSION
August 4, 1997

ADDRESS *(Number, Street, City, State and Zip Code)*
7000 Portage Road 9032-227-36
Kalamazoo, Michigan 49001

TELEPHONE NO. *(Include Area Code)*
(616) 833-0671

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued)
20-834

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(if any)*
minoxidil	5% Minoxidil Topical Solution

CODE NAME *(if any)*	CHEMICAL NAME
	2,4-pyrimidinediamine, 6-(1-piperidinyl), 3 oxide

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
solution	topical	5%

PROPOSED INDICATIONS FOR USE

ndrogenic alopecia

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, **NEW DRUG OR ANTIBIOTIC APPLICATIONS** *(21 CFR Part 314)*, **AND DRUG MASTER FILES** *(21 CFR 314.420)* **REFERRED TO IN THIS APPLICATION:**

IND

NDA 18-154 LONITEN® Tablets
NDA 19-501 ROGAINE® Topical Solution

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☑ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION

ORIGINAL APPLICATION ☐ RESUBMISSION ☐ GENERAL CORRESPONDENCE

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

CONTENTS OF APPLICATION

This application contains the following items: *(Check all that apply)*

	1. Index
	2. Summary (21 CFR 314.50 (c))
	3. Chemistry, manufacturing, and control section (21 CFR 314.50 (d) (1))
	4. a. Samples (21 CFR 314.50 (e) (1)) (Submit only upon FDA's request)
	b. Methods Validation Package (21 CFR 314.50 (e) (2) (i))
	c. Labeling (21 CFR 314.50 (e) (2) (ii))
	i. draft labeling *(4 copies)*
	ii. final printed labeling (12 copies)
	5. Nonclinical pharmacology and toxicology section (21 CFR 314.50 (d) (2))
	6. Human pharmacokinetics and bioavailability section (21 CFR 314.50 (d) (3))
	7. Microbiology section (21 CFR 314.50 (d) (4))
	8. Clinical data section (21 CFR 314.50 (d) (5))
	9. Safety update report (21 CFR 314.50 (d) (5) (vi) (b))
	10. Statistical section (21 CFR 314.50 (d) (6))
	11. Case report tabulations (21 CFR 314.50 (f) (1))
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	13. Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
	14. A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b) (2) or (j) (2) (A))
	15. OTHER *(Specify)*

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2. **Labeling regulations in 21 CFR 201.**
3. **In the case of a prescription drug product, prescription drug advertising regulations in 21 CFR 202.**
4. **Regulations on making changes in application in 21 CFR 314.70, 314.71, and 314.72.**
5. **Regulations on reports in 21 CFR 314.80 and 314.81.**
6. **Local, state and Federal environmental impact laws.**

this application applies to a drug product that FDA has proposed for scheduling under the controlled substances Act I agree not to market the roduct until the Drug Enforcement Administration makes a final scheduling decision.

AME OF RESPONSIBLE OFFICIAL OR AGENT	SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	DATE
aymond E. Dann, Ph.D., Director onsumer Healthcare, OTC Regulatory Affairs	E. D. C. Dann for RED	August 4, 1997

DDRESS *(Street, City, State, Zip Code)*	TELEPHONE NO. *(Include Area Code)*
7000 Portage Road Kalamazoo, Michigan 49001	(616) 833-0671

WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-
Telefax No. (616) 833-6612

July 28, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

GENERAL CORRESPONDENCE

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

In response to the Agency's telephone request on July 28, 1997, we are supplying a computer diskette containing the electronic text for the revised carton label, formatted in WordPerfect 5.2, and corresponds to the artwork recently submitted in NDA 20-834 amendment 006 on July 23, 1997

Text hardcopy is attached for the Agency's reference. Two desk copies of this letter, each including a diskette are provided to Robin Anderson, Regulatory Project Manager.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek
cc: 2 desk copies: Robin Anderson, Division of Dermatologic & Dental Drug Products (HFD-540)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: 12/31/95
See OMB Statement on Page 3.

FOR FDA USE ONLY	
DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	NDA/ANDA NO. ASS.

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314).*

NAME OF APPLICANT	DATE OF SUBMISSION
Pharmacia & Upjohn Company	July 28, 1997
ADDRESS *(Number, Street, City, State and Zip Code)* 7000 Portage Road 9032-227-369 Kalamazoo, Michigan 49001	TELEPHONE NO. *(Include Area Code)* (616) 833-0671
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued) 20-83[illegible]

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
JUL 29 1997
MEGA DOC RM

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(if any)*
minoxidil	5% Minoxidil Topical Solution

CODE NAME *(if any)*	CHEMICAL NAME
	2,4-pyrimidinediamine, 6-(1-piperidinyl), 3 oxide

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
solution	topical	5%

PROPOSED INDICATIONS FOR USE

Androgenic alopecia

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

IND

NDA 18-154 LONITEN® Tablets
NDA 19-501 ROGAINE® Topical Solution

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☒ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION

☐ ORIGINAL APPLICATION ☐ RESUBMISSION ☐ GENERAL CORRESPONDENCE

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

July 23, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 006

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting a revised draft carton label (Attachment 1) for ROGAINE® Extra Strength for Men for the Agency's consideration in response to the suggestions made by the committee at the Nonprescription Drug Advisory Committee (NDAC), held on July 16, 1997. For your reference, we have also attached the previous carton label version (Attachment 2), which was provided to the NDAC in the briefing document, as well as distributed to the committee as mock ups packages.

For a summary of the NDAC's suggested changes and description of the revisions, please see table 1. There were additional suggested changes from the NDAC which we did not believe to be appropriate, please see table 2 for this list and our reasons for not making these changes.

We propose to meet with the Agency as soon as possible to discuss these and any other labeling issues in order to expedite the process.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

cc: 12 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

PHARMACIA & UPJOHN COMPANY
7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

Logged In
DPE III
HFD - 880
Date: 9/4/97

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
AUG 0 5 1997
MEGA DOC RM

August 4, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 008

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting a revised draft bottle label (Attachment 1) for ROGAINE® Extra Strength for Men for the Agency's consideration. We have tried to match this proposed label with the corresponding sections of the proposed draft carton label, submitted in amendment 006 on July 23, 1997. For your reference, we have also attached the previous bottle label version (Attachment 2), which was provided to the NDAC in the briefing document, as well as submitted in NDA 20-834 on February 28, 1997.

For a summary of the proposed revisions, please see table 1. A diskette containing a Word Perfect text file of the proposed draft bottle label is enclosed in two desk copies (only) provided to Mary Jean Kosma-Fornaro.

As with amendment 006, we propose to meet with the Agency as soon as possible to discuss these and any other labeling issues in order to expedite the process.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

cc: 12 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs
Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

November 3, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 012

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Please see the attached, regarding minoxidil bulk drug needs between 1997 and 2001, which was faxed to you on October 30, 1997.

Please contact me at (616) 833-0671 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED: ECB:cek

AF

PHARMACIA & UPJOHN COMPANY

ORIGINAL

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs
Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

October 29, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 011

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

With reference to the above product, NDA 20-834, ROGAINE® Extra Strength for Men, and the teleconference held on October 24, 1997 with Drs. Weintraub, Bowen and Aurecchia concerning the proposed labeling, we are submitting 15 copies of the revised labeling artwork incorporating the FDA's suggested changes. We have also incorporated a number of very minor editorial changes involving grammar and spelling.

Final printed labeling prepared using this artwork will be submitted as soon as possible for all packaging components.

Please contact me at (616) 833-0671 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Carl M. DeJulio for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

1 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Millie Wright, Division of OTC Drug Evaluation (HFD 560)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

BL

ORIG AMENDMENT

DUPLICATE

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs
Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

October 23, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 010

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting our suggested labeling changes in reference to your fax of 10/22/97.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

4 Copies: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
1 Copy: Millie Wright, Division of OTC Drug Evaluation (HFD 560)

AMENDMENT

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

July 29, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 007

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting two overheads which are in addition to the fourteen submitted as part of Amendment No. 004 on July 22, 1997.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

E. C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ATTACHMENTS

cc: 2 copies: Robin Anderson, Division of Dermatologic & Dental Drug Products (HFD-540)
1 copy: Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG FOR HUMAN USE OR AN ANTIBIOTIC DRUG FOR HUMAN USE
(Title 21, Code of Federal Regulations, 314)

Form Approved: OMB No. 0910-0001.
Expiration Date: 12/31/95
See OMB Statement on Page 3.

FOR FDA USE ONLY

DATE RECEIVED	DATE FILED
DIVISION ASSIGNED	**NDA/ANDA NO. ASS.**

NOTE: No application may be filed unless a completed application form has been received *(21 CFR Part 314).*

NAME OF APPLICANT	DATE OF SUBMISSION
Pharmacia & Upjohn Company	July 29, 1997
ADDRESS *(Number, Street, City, State and Zip Code)*	**TELEPHONE NO.** *(Include Area Code)*
7000 Portage Road 9032-227-369 Kalamazoo, Michigan 49001	(616) 833-0671
	NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER (if previously issued)
	20-834

DRUG PRODUCT

ESTABLISHED NAME *(e.g., USP/USAN)*	PROPRIETARY NAME *(if any)*
minoxidil	5% Minoxidil Topical Solution

CODE NAME *(if any)*	CHEMICAL NAME
	2,4-pyrimidinediamine, 6-(1-piperidinyl), 3 oxide

DOSAGE FORM	ROUTE OF ADMINISTRATION	STRENGTH(S)
solution	topical	5%

PROPOSED INDICATIONS FOR USE

Androgenic alopecia

LIST NUMBERS OF ALL INVESTIGATIONAL NEW DRUG APPLICATIONS *(21 CFR Part 312)*, NEW DRUG OR ANTIBIOTIC APPLICATIONS *(21 CFR Part 314)*, AND DRUG MASTER FILES *(21 CFR 314.420)* REFERRED TO IN THIS APPLICATION:

IND

NDA 18-154 LONITEN® Tablets
NDA 19-501 ROGAINE® Topical Solution

INFORMATION ON APPLICATION

TYPE OF APPLICATION *(Check one)*

☐ THIS SUBMISSION IS A FULL APPLICATION *(21 CFR 314.50)* ☐ THIS SUBMISSION IS AN ABBREVIATED APPLICATION (ANDA) (21 CFR 314.55)

IF AN ANDA, IDENTIFY THE APPROVED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

NAME OF DRUG	HOLDER OF APPROVED APPLICATION

TYPE SUBMISSION *(Check one)*

☐ PRESUBMISSION ☑ AN AMENDMENT TO A PENDING APPLICATION ☐ SUPPLEMENTAL APPLICATION

☐ ORIGINAL APPLICATION ☐ RESUBMISSION ☐ GENERAL CORRESPONDENCE

SPECIFIC REGULATION(S) TO SUPPORT CHANGE OF APPLICATION *(e.g., Part 314.70(b)(2)(iv))* _____

PROPOSED MARKETING STATUS *(Check one)*

☐ APPLICATION FOR A PRESCRIPTION DRUG PRODUCT *(Rx)* ☐ APPLICATION FOR AN OVER-THE-COUNTER PRODUCT *(OTC)*

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

July 22, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 005

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting revised pages for Item 3, Part IIF, Drug Product, which adds an alternative bottle label which is referred to as "pressure sensitive" bottle label. This new label will be an alternative to the current FUJI "sleeve" bottle label which is currently described in the CMC section of NDA 20-834. The color graphics, printed text style and the general appearance of both bottle labels are similar. We would like to add the alternative label because the lead times for supply delivery are much shorter and it allows us more flexibility in making revisions upon short notice.

A proposal for this amendment was previously provided in draft form to the Agency by fax on June 25, 1997, and we requested feedback from the Reviewing Chemist as to whether this change would interfere with the NDA CMC review currently underway. It is our understanding from the Agency's response, communicated by telephone on July 18, 1997, that there is minimal impact, if any.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

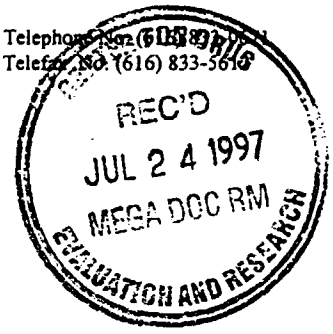
cc: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0438
Telefax No. (616) 833-5618



July 22, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 004

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting one copy of the fourteen overheads which were presented in response to committee member questions at the July 16, 1997 NDAC for ROGAINE® Extra Strength for Men.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

cc: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

June 19, 1997

NEW CORRESPONDENCE

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 003

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Regarding the above mentioned NDA 20-834, we are submitting for your information the enclosed Intent to Heed Study Among Women, Supplemental Control Arm (MRD# 9705-HC-12). This report is also included in the NDAC briefing document, Rogaine® Extra Strength For Men, dated July 16, 1997, which was supplied to the FDA (Robin Anderson) and the NDAC (Andrea Neal) on June 18, 1997.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil A. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

REVIEWS COMPLETED
CSC ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO
CSO INITIALS DATE

RED:ECB:cek

cc: Robin Anderson, Division of Dermatologic & Dental Drug Products (HFD-540)
Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

May 28, 1997

Division of Dermatologic & Dental
Drug Products (HFD-540)
Document Control Room
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, MD 20850

Attn: Jonathan Wilkin, M.D.

Re: NDA 20-834
5% Minoxidil Topical Solution
ROGAINE® Extra Strength for Men

General Correspondence

Dear Dr. Wilkin:

At the teleconference on May 20, 1997, the Agency informed P&U that a Nonprescription Drug Advisory Committee (NDAC) meeting is scheduled on Wednesday, July 16, 1997, to discuss the remaining unresolved issues for direct OTC application NDA 20-834, ROGAINE EXTRA STRENGTH FOR MEN (5% Minoxidil Topical Solution). In preparation for the NDAC, we request FDA's timely input regarding the following items:

1. Please comment on the attached draft outline for the NDAC briefing document. Portions of this outline also represents the NDAC presentation, depending on the nature of specific issues that FDA requests the NDAC to address.

2. How much detail should the NDAC briefing document contain regarding general efficacy and safety for ROGAINE 5%, since FDA has already considered the Rx NDA to be approvable for use in men? Our intention is to include a brief review of these topics and focus on the perceived safety issues related to OTC use.

3. How might P&U and FDA coordinate NDAC presentations so as to minimize duplication?

4. What are the specific questions for the NDAC? **It is critical that we have advance notice of the questions so that our briefing document and presentation will address all of the issues.**

Although P&U is aware of the FDA labeling concerns (potential for use by women and comprehension of dosing/selection by men), it is not clear what other specific concerns the Agency has for this product. Dr. Wilkin stated some general reasons at the May 20, 1997 teleconference for holding an NDAC such as: high public awareness/interest in products like ROGAINE, gender specific product in higher strength (from a more general perspective) and the uniqueness of a direct OTC approval. It would be very useful for us to know what policy and/or specific issues FDA wishes the committee to discuss.

Should you have any questions concerning the content of this correspondence, please contact Emil C. Berro at (616) 833-0438.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

cc: Dr. Debra Bowen (HFD-560)
Robin Anderson (HFD-540)

ORIGINAL

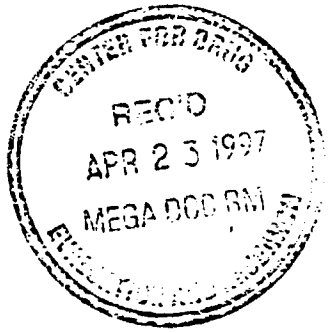
PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
Raymond E. Dann, Ph.D., Director
OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

BC
ORIG AMENDMENT



April 22, 1997

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE

Division of Dermatologic & Dental
Drug Products (HFD-540)
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

AMENDMENT NO. 002

RE: NDA 20-834
ROGAINE® Extra Strength for Men
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

This letter is to notify the Food and Drug Administration (FDA) that Pharmacia & Upjohn manufacturing and packaging facilities, described in NDA 20-834, are ready for pre-approval inspection. Also, we wish to note as previously stated in the cover letter for NDA 20-834, dated February 28, 1997, a field copy of the Item 3, Chemistry, Manufacturing and Controls (CMC) section of NDA 20-834 has been provided to the Detroit District Office. This CMC document is nearly identical to that previously submitted in NDA The minor differences between these CMC sections are described in "notes to the reviewer", which immediately follows the table of contents, provided in volume 1.3. Additionally, the "notes to reviewer" also contain our responses to the CMC questions which were included in the approvable letter for NDA . Finally, we note that a facilities inspection was conducted by the Detroit District Office on June 4-6, 1996 and a letter was received from the Agency dated July 2, 1996, confirming acceptance of preapproval inspection.

We also wish to identify those portions of the Environmental Impact Assessment, contained in Part V in NDA volume 1.4 and again repeated in volume 1.5, which are releasable under Freedom of Information (FOI). In this regard, only Appendix 7," Minoxidil: Materials Used in the Manufacture", is not releasable.

Please contact Emil Berro at (616) 833-0438 with any questions regarding this submission.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

ORIGINAL

PHARMACIA & UPJOHN COMPANY

7000 Portage Road
Kalamazoo, MI 49001-0199

Pharmacia & Upjohn Consumer Healthcare
Office of:
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OTC Regulatory Affairs

Telephone No. (616) 833-0671
Telefax No. (616) 833-5612

NC
NEW CORRESP

March 10, 1997

Division of Dermatologic and
Dental Drug Product (HFD-540)
Office of Drug Evaluation V
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

GENERAL CORRESPONDENCE

Re: NDA 20-834
ROGAINE® EXTRA STRENGTH
FOR MEN
(5% Minoxidil Topical Solution)

Dear Sir/Madam:

Enclosed please find one diskette containing electronic text for the carton label, bottle label and Consumer Leaflet, in addition to four copies of labeling artwork, per request of Robin Anderson, Project Manager, Division of Dermatologic and Dental Drug Products.

Should you have any questions concerning the contents of this application, please contact Emil C. Berro at (616) 833-0438.

Sincerely,

Pharmacia & Upjohn Consumer Healthcare

Emil C. Berro for

Raymond E. Dann, Ph.D.
Director, OTC Regulatory Affairs

RED:ECB:cek

cc: Archival
Robin Anderson (HFD-540)

REVIEWS COMPLETED

CSO ACTION:
☐ LETTER ☐ N.A.I. ☐ MEMO

CSO INITIALS DATE