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	DATE OF SUBMISSION
Pharmacia & Upjohn Company	11/13/97
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

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)*
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	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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	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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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:

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

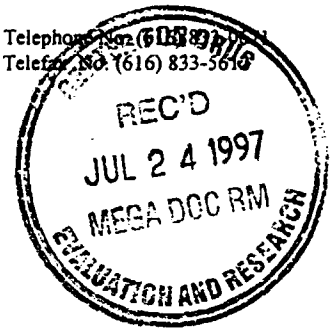
cc: Mary Jean Kozma-Fornaro, Division of Dermatologic & Dental Drug Products (HFD-540)
Carol Doyle, Division of OTC Drug Evaluation (HFD 560)

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

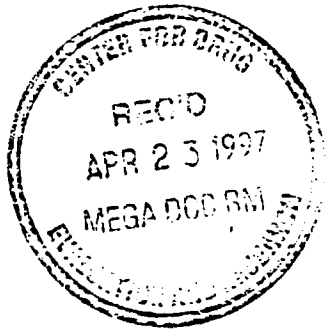
PHARMACIA & UPJOHN COMPANY

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:
Raymond E. Dann, Ph.D., Director
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