CENTER FOR DRUG EVALUATION AND RESEARCH

**Approval Package for:**

**APPLICATION NUMBER:**

19-501/S025

<table>
<thead>
<tr>
<th><strong>Trade Name:</strong></th>
<th>Men’s Rogaine Regular Strength and Women’s Rogaine topical solutions</th>
</tr>
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<tbody>
<tr>
<td><strong>Generic Name:</strong></td>
<td>2% minoxidil</td>
</tr>
<tr>
<td><strong>Sponsor:</strong></td>
<td>Pharmacia and Upjohn</td>
</tr>
<tr>
<td><strong>Approval Date:</strong></td>
<td>June 21, 2005</td>
</tr>
<tr>
<td><strong>Purpose:</strong></td>
<td>Proposes the inclusion of the phrase “#1 Dermatologist Recommended Brand” within a “seal” graphic on the Principal Display Panels (PDPs) for unscented Men’s Rogaine, and both scented and unscented Women’s Rogaine products</td>
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<tr>
<td>Proprietary Name Review(s)</td>
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<td>Administrative/Correspondence Document(s)</td>
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</table>
APPLICATION NUMBER:
19-501/S025

APPROVAL LETTER
Pharmacia and Upjohn, A Pfizer Company  
Attention:  
Dina R. Russello, Director  
Global Regulatory Affairs  
201 Tabor Road  
Morris Plains, NJ 07950

Dear Ms. Russello:

Please refer to your supplemental new drug application (S-025) dated December 20, 2004, received December 22, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Men’s Rogaine® Regular Strength and Women’s Rogaine® (2% minoxidil) topical solutions.

We acknowledge receipt of your submissions dated May 23 and June 7, 2005.

This supplemental new drug application proposes the inclusion of the phrase “#1 Dermatologist Recommended Brand” within a “seal” graphic on the Principal Display Panels (PDPs) for unscented Men’s Rogaine®, and both scented and unscented Women’s Rogaine® products.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container, carton labels, and patient package insert submitted on December 20, 2004), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format - NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission “FPL for approved supplement NDA 19-501/S-025.” Approval of this submission by FDA is not required before the labeling is used.

We also refer to your supplemental new drug application (S-020) dated March 25, 2002, received on March 25, 2002. This application (S-020) provided for labeling in Drug Facts format with new warnings and other modifications to the product label and package insert for Men’s Rogaine® and Women’s Rogaine® (2% minoxidil) topical solutions. The approved draft labeling for application S-025 incorporates the changes proposed under S-020 and the revisions required in our February 3, 2003, approvable letter for S-020. Supplemental application S-020 is hereby superseded by the approval for application S-025. Supplemental application S-020 will be closed and retained in our files.
If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Tia Frazier, Regulatory Project Manager, at (301) 827-2271.

Sincerely,

[See appended electronic signature page]
Curtis Rosebraugh, M.D., M.P.H.
Acting Division Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

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Curtis Rosebraugh
6/21/05 03:07:31 PM
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
19-501/S025

LABELING
Who may use Men's Rogaine Regular Strength?

Rogaine may be appropriate for:
- Men who are bald or have thinning hair.
- Men who are at least 18 years old.
- Men who are experiencing gradual thinning hair or gradual hair loss on the top or sides of the head.
- Men who have hereditary thinning or hair loss that begins early and may become noticeable in 5 years or after years of gradual loss.
- Rogaine is for men with hair loss or thinning that begins at the top or sides of the scalp (as shown below).
- Frontal hair growth has not been demonstrated in clinical trials.
- Rogaine is more likely to regrow hair in men with hair loss in the area shown below.
- Many men have extra hair loss than shown.
- Rogaine may not work.
- Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss.
- If there is no family history of gradual thinning or gradual hair loss, or hair loss is in patches, talk to your doctor.

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
<th>NDC Code</th>
<th>Size</th>
<th>Price</th>
<th>Unit of Measure</th>
</tr>
</thead>
</table>
| 22459        | Men's Rogaine | 0999.3776-01 | 2 x 6% | $89.49 | Bottle  
| 22455        | Men's Rogaine 4% | 0999.3776-01 | 1 x 5% | $27.99 | Bottle  
| 22456        | Men's Rogaine 5% | 0999.3776-01 | 1 x 5% | $36.99 | Bottle  
| 22457        | Men's Rogaine 5% | 0999.3776-01 | 1 x 6% | $62.49 | Bottle  
| 22461        | Men's Rogaine 4% | 0999.3776-01 | 1 x 6% | $99.99 | Bottle  
| 22460        | Men's Rogaine | 0999.3776-01 | 1 x 6% | $199.99 | Bottle  

745568-81873-12979(Men'sRogaine)  
3 at 01 PM 9/10/24 
(b)(4)
Who should NOT use Men's Rogaine Regular Strength?
Rogaine® will not please it or improve
hair loss which may occur with the
use of some prescription and non-
prescription medications, certain
severe nutritional problems, thin
body hair, explosive strains. A
relative, low thyroid status,
psoriasis, psoriasis, chemotherapy, or
diseases which cause scarring of
the scalp. Also, Rogaine® will not
improve hair loss due to:
• Damage from the use of hair
care products which cause:

- Scarring or deep burns of
  the scalp.
- Hair grooming methods such as
  combing or pigtails which
  require pulling the hair tightly
  from the scalp.

You should ask your doctor if
you are unsure of the cause of
your hair loss.

Will Men's Rogaine Regular
Strength work for me?
The amount of hair growth
is different for each person.
Not everyone will respond to
Rogaine®. The response to
Rogaine® cannot be predicted.
No one will be able to gain back
all their hair.

You may respond better if you
have been losing your hair for a
short period of time or have little
shed hair loss.

In clinical studies of mostly white
men aged 18-40 years with
moderate degrees of hair loss, the
following response to Rogaine
was reported:

Rogaine Response in Men
Percent reporting hair regrowth

<table>
<thead>
<tr>
<th>Hair Regrowth</th>
<th>100%</th>
<th>90%</th>
<th>80%</th>
<th>70%</th>
<th>60%</th>
<th>50%</th>
<th>40%</th>
<th>30%</th>
<th>20%</th>
<th>10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 weeks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 weeks</td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Dispensary Unit 1965

Composition Unit 1964

Black

Composition Unit 1966

Black
25% of men report moderate to dense hair growth after using Rogaine for 4 months (20% had moderate to dense regrowth; 33% had minimal regrowth). This compares with 1% of men reporting hair regrowth after using the placebo. The liquid without medication in it. For 4 months (31%) had moderate to dense regrowth; 31% had minimal regrowth.

What Minimal, Moderate and Dense Hair Regrowth Will Mean For You

<table>
<thead>
<tr>
<th>Number of Hair</th>
<th>Hair Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 hair in 1 inch</td>
<td>No change</td>
</tr>
<tr>
<td>2 hairs in 1 inch</td>
<td>Very fine</td>
</tr>
<tr>
<td>3 hairs in 1 inch</td>
<td>Fine</td>
</tr>
<tr>
<td>4 hairs in 1 inch</td>
<td>Fine to thick</td>
</tr>
<tr>
<td>5 hairs in 1 inch</td>
<td>Medium</td>
</tr>
<tr>
<td>6 hairs in 1 inch</td>
<td>Medium to thick</td>
</tr>
<tr>
<td>7 hairs in 1 inch</td>
<td>Thick</td>
</tr>
</tbody>
</table>

Can Men's Rogaine Regular Strength be used to prevent hair loss?

We do not know if Rogaine will prevent hair loss.

How soon can I expect results from using Men's Rogaine Regular Strength?

Some normal hair usually grows only 1/2 to 1 inch per month. Hair regrowth with Rogaine also takes time. Generally, new hair growth is slow for a Rogaine user. Continued use 2 times a day for at least 4 months is usually needed before you notice hair regrowth. If you do not see hair regrowth in 8 months, stop using Rogaine and see your doctor.

When you first begin to use Rogaine, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after 2 weeks, see your doctor.

If Men's Rogaine Regular Strength is working, what will the hair look like?

At first, hair growth may be not, or thin, or colorless hair. After 4 months use, the new hair should be the same color and thickness as the other hair on your scalp.

How long do I need to use Men's Rogaine Regular Strength?

If you respond to Rogaine, you will need to use it 2 times a day to keep and continue the hair regrowth. Up to 12 months of use may be needed to see your best results from Rogaine.
What happens if I completely stop using Men's Rogaine
Regular Strength? Will I keep the new hair?
Continuous use of Rogaine is needed to maintain hair regrowth.
If you stop using Rogaine, the normal hair loss process will start again. You will probably lose your newly grown hair in three to four months.

What is the dosage of Men's Rogaine Regular Strength?
You should apply a dose (1 mL) of Rogaine directly onto the scalp in the fall off area, TWICE TIMES
A DAY, for example, once in the morning and once at night. Each bottle should last about one month if used as directed. Please refer to the "DIRECTIONS FOR USE" section of this booklet.

What if I miss a dose or forget to use Men's Rogaine Regular Strength?
If you miss one or two daily doses of Rogaine, just continue with your next dose. You should not make up for missed doses.

Can I use Men's Rogaine Regular Strength more than two times a day? Will it work faster, better?
No, Rogaine will not work faster or better if used more than 2 times a day. Studies have been carefully conducted to determine the correct amount of Rogaine needed to get

the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chance of side effects.

What are the most common side effects of Men's Rogaine Regular Strength?
The most common side effects are itching and other skin irritations of the treated areas of the scalp. Rogaine contains alcohol, which could cause burning or irritation of the eyes or sensitive skin areas. If Rogaine accidentally gets into these areas, rinse with large amounts of cool water. Contact your doctor if irritation persists.

What kind of shampoo should I use with Men's Rogaine Regular Strength?
If you wash your scalp before applying Rogaine, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.? Yes. There is no need to change your usual hair care routine when using Rogaine. However, you should apply Rogaine that is wet for it to dry before applying your styling aids.
Can I have my hair colored or permed or use hair relaxers while using Men's Rogaine® Regular Strength?
Yes. We have no information that these treatments change the effect of Rogaine. However, to avoid possible scalp irritation, you should make sure all of the Rogaine has been washed out of the hair and scalp before using these chemicals.

Can I apply Men's Rogaine® Regular Strength and wash my hair an hour later?
No. For Rogaine to work best, you should allow Rogaine to remain on the scalp for about 4 hours before washing.

Can I go swimming or out in the rain?
Yes. Avoid washing off the Rogaine. It is possible, apply Rogaine to a dry scalp after swimming or wash about 4 hours after application before going swimming. Do not let your scalp get wet after the 4 hours after applying Rogaine.

Can Men's Rogaine® Regular Strength produce unwanted hair?
Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the handling of Rogaine.

In rare cases, other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by an unusual condition not related to the use of Rogaine.

If you experience unwanted hair, stop use immediately and see your doctor for recommendations about appropriate treatment. After stopping use of Rogaine, the unwanted hair, if caused by the use of Rogaine, should go away over time.

You can take steps to decrease the chances for unwanted hair growth:
- Limit the application of Rogaine to the scalp. If you use your hands to apply Rogaine, wash your hands thoroughly afterward, and do not allow sufficient drying time. Usually 2 to 4 hours before going to bed, apply your regular application of Rogaine.

Can I use Men's Rogaine® Regular Strength for baldness or hair loss in babies and children?
No. Rogaine must not be used to treat baldness in hair loss in babies or children.

Are there any special warnings about the use of Men's Rogaine® Regular Strength?
For external use only.
Flammable: Keep away from fire or flame.
Do not use if:
- your degree of hair loss is more than that shown on page 2 and 3 of this booklet, because this product may not work for you.
- you have no family history of hair loss.
- your hair loss is sudden and/or patchy.
- you do not know the reason for your hair loss.
- you are under 18 years of age.
- you use other medicines on the scalp.
- you have a doctor before use if you have heart disease.

When using this product:
- do not apply on other parts of the body.
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture.
- it takes time to regain hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if:
- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hairline or face swells
- scalp irritation or redness occurs
- unexplained hair growth occurs
- you do not see hair regrowth in 4 months.

May be harmful if used when pregnant or breast-feeding.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What factors may increase the risk of serious side effects with Men's Rogaine Regular Strength?
- hair growth on the sides of the scalp, the face, or other parts of the body.

Directions for Use:
1. Remove the cap. To remove, firmly squeeze on bottle and remove cap and pull off the overcap.
2. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
3. Part your hair in the area of hair thinning loss. Follow the instructions below for using the shampoo applicator and apply one ml, 2 times a day directly onto the scalp in the hair loss area. Do not
[Image]
<table>
<thead>
<tr>
<th>Longboard Unit 2768</th>
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</thead>
<tbody>
<tr>
<td><strong>Product</strong></td>
<td><strong>Description</strong></td>
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<tr>
<td>27681</td>
<td>Longboard Unit 2768</td>
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<tr>
<td><strong>Components</strong></td>
<td><strong>Quantity</strong></td>
</tr>
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<td>700-235</td>
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<td><strong>Description</strong></td>
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<tr>
<td>Marriott H-5 1&amp;4</td>
<td>0000-3778-01</td>
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<table>
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<tbody>
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<td>Compression Unit 2544</td>
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<td><strong>Quantity</strong></td>
</tr>
<tr>
<td>816-735 107</td>
<td>1</td>
</tr>
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<td><strong>Details</strong></td>
<td><strong>Description</strong></td>
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<td><strong>Material</strong></td>
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</table>

| 697717            | 2 x 5.5 |
|                  | 0-10-04 |

| 697717            | 2 x 5.5 |
|                  | 0-10-04 |
Women's Rogaine

2% Minoxidil Topical Solution

Save booklet for future reference.

- Hair regrowth treatment
- Previously available only by prescription

Over 30 million American women experience hair thinning or hair loss, so you're not alone. Women's Rogaine contains the only ingredient that is medically proven effective to help regrow hair in women. Please read this booklet carefully. It will help you understand how to use Rogaine and what to expect from its use. If you have any questions after reading this booklet, or anytime while using Women's Rogaine, you should ask your health care professional or call us at 1-800-ROGAINE (1-800-764-2463). You can also visit our website at rogaine.com.

What is Women's Rogaine?
Rogaine is a colorless, liquid medication for use only on the top of the scalp to help regrow hair.

Who may use Women's Rogaine?
Women's Rogaine may be appropriate for you if you are an adult who is at least 18 years old and experiencing general thinning of hair on the top of the head. The common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss. Women's Rogaine is for general thinning of hair on the top of the head of adults who can understand page 2. Rogaine has been shown to regrow hair in women with the degree of hair loss shown. If women have more hair loss than shown, Rogaine may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.
Who should NOT use Women's Rogaine?
Rogaine will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron, excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid states (hypothyroidism), chemotherapy, or disease which cause hair loss from the scalp. Also, Rogaine will not improve hair loss due to:
- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as cornrowing or weavalls which require pulling the hair tightly back from the scalp.

Do not use Rogaine F hair loss is patchy as shown below.

You should ask your doctor if you are unsure of the cause of your hair loss.
Will Women’s Rogaine work for me?
The amount of hair regrowth is different for each person. Not everyone will respond to Rogaine. The response to Rogaine cannot be predicted. No one will be able to grow back all their hair.
In clinical studies of mostly white women aged 18-45 years with mild to moderate degree of hair loss, the following response to Rogaine was reported:

Female Response to Rogaine
Percent reporting hair regrowth

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Moderate Response</th>
<th>Minimal Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 months</td>
<td>15%</td>
<td>4%</td>
</tr>
<tr>
<td>1 year</td>
<td>20%</td>
<td>5%</td>
</tr>
</tbody>
</table>

19% of women reported moderate hair regrowth after using Rogaine for 6 months (15% had moderate response; 4% had minimal regrowth). This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil in it, for 9 months (7% had moderate response; 23% had minimal regrowth).

What Minimal, Moderate and Dense Hair Regrowth Will Mean For You

<table>
<thead>
<tr>
<th>Hair Density</th>
<th>Maneuver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some hair</td>
<td>Some hair</td>
</tr>
<tr>
<td>Not enough to cover thinning areas.</td>
<td>Not enough to cover thinning areas.</td>
</tr>
<tr>
<td>Hair in thinning areas is not close together, but are not as close together as hair on the rest of the head.</td>
<td>Hair in thinning areas grow at closely together as hair on the rest of the head.</td>
</tr>
</tbody>
</table>

Can Women’s Rogaine be used to prevent hair loss?
We do not know if Rogaine will prevent hair loss. How soon can I expect results from using Women’s Rogaine?
Since normal hair usually grows only ½ to 1 inch per month, hair regrowth with Rogaine also takes time. Generally new hair growth is slow for a Rogaine user. Continued use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth.
If you do not see hair regrowth in 4 months, stop using Rogaine and see your doctor.
When you first begin to use Rogaine, your hair loss may continue for up to 2 weeks. This hair loss is temporary. If you continue to lose hair after two weeks, see your doctor.

If Women’s Rogaine is working, what will the hair look like?
At first, hair growth may be soft, downy, colorless hair. After further use, the new hair should be the same color and thickness as the other hair on your scalp.

How long do I need to use Women’s Rogaine?
If you respond to Rogaine, you need to use it 2 times a day to keep and continue the hair regrowth. Up to 9 months of usage may be needed to see your best results from Rogaine.

What happens if I completely stop using Women’s Rogaine?
Will I keep the new hair?
Continuous use of Rogaine is needed to maintain hair regrowth. If you stop using Rogaine, the normal hair loss process will start again. You will probably lose your newly regrown hair in three to four months.

What is the dosage of Women’s Rogaine?
You should apply a dose (1 mL) of Rogaine directly onto the scalp in the hair loss area two times a day:

1. Morning and 1 night at night.
Each bottle should last about one month, if used as directed. Please refer to the "Disclaimers for Use" section of this booklet.

What if I miss a dose or forget to use Women’s Rogaine?
If you miss one or two daily doses of Rogaine, just continue with your next dose. You should not make up for missed doses.

Can I use Women’s Rogaine more than two times a day?
Rogaine will not work faster or better if used more than two times a day. Studies by Pharmacia have been carefully conducted to determine the correct amount of Rogaine needed to get the best results. More frequent use or larger doses have not been shown to speed up hair growth and may increase your chances of side effects.

What are the most common side effects with Women’s Rogaine?
The most common side effects are itching and other skin irritations of the treated area of the scalp.
Rogaine contains alcohol, which could cause burning or irritation of the eyes or sensitive skin areas. If Rogaine accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

What kind of shampoo should I use with Women's Rogaine? If you wash your scalp before applying Rogaine, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.? Yes. There is no reason to change your usual hair care routine when using Rogaine. However, you should only apply Rogaine first and wait for it to dry before applying your styling aids.

Can I have my hair colored or perm or use hair relaxers while using Women's Rogaine? Yes. We have no information that these treatments change the effect of Rogaine. However, to avoid possible scalp irritation, you should make sure all of the Rogaine has been washed off the hair and scalp before using these chemicals.

Can I apply Women's Rogaine and wash my hair an hour later? No. For Rogaine to work best, you should allow Rogaine to remain on the scalp for about 4 hours before washing.

Can I go swimming or cut In the rain? Yes. Avoid washing off the Rogaine. If possible, apply Rogaine to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Rogaine.

Can Women's Rogaine produce unwanted hair? Although unwanted hair growth has been reported on the face and other parts of the body, such reports are rare and infrequent. The unwanted hair growth may be caused by the transfer of Rogaine to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Rogaine.

If you experience unwanted hair, discontinue using Rogaine and see your doctor for recommendations about appropriate treatment. After stopping use of Rogaine, the unwanted hair, if caused by the use of Rogaine, should go away over time.
You can take steps to decelerate the chances for unwanted hair growth: 1) limit the application of Rogaine only to the scalp, 2) if you use your hands to apply Rogaine, wash your hands thoroughly afterwards, and 3) allow sufficient drying time (usually 2 to 4 hours before going to bed) after your nighttime application of Rogaine.

Can I use Women's Rogaine for baldness or hair loss in babies and children? No. Rogaine must not be used to treat baldness or hair loss in babies or children.

Are there any special warnings about the use of Women's Rogaine? For external use only

Flammable. Keep away from fire or flame

Do not use if
• your degree of hair loss is more than that shown on page 3 of this booklet. Because this product may not work for you
• you have no family history of hair loss
• your hair loss is sudden and/or patchy
• your hair loss is associated with childbirth
• you do not know the reason for your hair loss

• you are under 18 years of age.
• Do not use on babies and children.
• your scalp is red, irritated, infected, inflamed, or painful
• you use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product
• do not apply on other parts of the body
• avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water
• some people have experienced changes in hair color and/or texture
• it takes time to see results. You may need to use this product 2 times a day for at least 4 months before you see results
• the amount of hair regrowth is different for each person. This product will not work for everyone

Stop use and ask a doctor if
• chest pain, rapid heartbeat, faintness, or dizziness occurs
• sudden, unexplained weight gain occurs
• your hands or feet swell
• scalp irritation or redness occurs
• unwanted facial hair growth occurs
• You do not see hair regrowth in 4 months.

May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What factors may increase the risk of serious side effects with Women's Rogaine?
Rogaine should be applied only to the scalp. The risk of side effects may be greater when Rogaine is applied to other parts of the body.

Directions for Use
1. Remove the overcap. Place the dropper tip on bottle and overcap and pull off the overcap.
2. Remove the inner cap. Place your hand on the base of the dropper and turn in direction of the arrows on the cap.
3. Part your hair in the area of hair thinning/loss. Follow the instructions below for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Rogaine.

Using the Dropper Applicator
1. Squeeze the rubber bulb and insert the dropper into the bottle. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
2. Rest, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
3. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.
If you have any other questions, ask your health care professional or call us at 1-800-ROGAINE (1-800-764-8436). You can also visit our website at rogaine.com.

Store at Controlled Room Temperature 20° to 25°C (68° to 77°F).

Save this booklet for future reference.
Women's Rogaine®
2% Minoxidil Topical Solution
Spring Bloom™ Scent
Save booklet for future reference:
- Women's Rogaine with Spring Bloom™ Scent, the only treatment proven to regrow hair in women, with a soft floral fragrance.
- Hair regrowth treatment.
- Previously available only by prescription.
Over 30 million American women experience hair thinning or hair loss, so you're not alone. Women's Rogaine contains the only ingredient that is medically proven effective to help regrow hair in women.
Please read this booklet carefully. It will help you understand how to use Rogaine and what to expect from its use. If you have any questions after reading this booklet, or anytime while using Women's Rogaine, you should ask your health care professional or call us at 1-800-ROGAINE (1-800-766-4363). You can also visit our website at rogaine.com.

1

What is Women's Rogaine®?
Rogaine is a colorless liquid medication for use only on the top of the scalp to help regrow hair.

Who may use Women's Rogaine®?
Women's Rogaine® may be appropriate for you if you are an adult who is at least 18 years old and experiencing gradual thinning hair or gradual hair loss on the top of the head. This common hereditary thinning or hair loss process begins slowly and may become noticeable only after years of gradual loss.

Women's Rogaine is for general thinning of hair on the top of the scalp as shown on the next page. Rogaine has been shown to regrow hair in women with the degree of hair loss shown. If women have more hair loss than shown, Rogaine may not work.

Many of those experiencing hair loss have other family members with gradual thinning hair or hair loss. If there is no family history of gradual thinning or gradual hair loss, or hair loss is patchy, talk to your doctor.
Who should NOT use Women's Rogaine?
Rogaine will not prevent or improve hair loss related to pregnancy, the use of some prescription and non-prescription medications, certain severe nutritional problems (very low body iron; excessive vitamin A intake), the recently discontinued use of birth control pills, low thyroid status (hypothyroidism), chemotherapy, or diseases which cause scarring of the scalp. Also, Rogaine will not improve hair loss due to:

- damage from the use of hair care products which cause scarring or deep burns of the scalp.
- hair grooming methods such as shaving or porcupines which may be pulling the hair tightly back from the scalp.

Do not use Rogaine if hair loss is patchy as shown below.

You should ask your doctor if you are unsure of the cause of your hair loss.
Will Women's Rogaine work for me? The amount of hair regrowth is different for each person. Not everyone will respond to Rogaine. The response to Rogaine cannot be predicted. No one will be able to grow back all their hair. In clinical studies of mostly white women aged 18-45 years with mild to moderate degrees of hair loss, the following response to Rogaine was reported:

**Female Response to Rogaine**

<table>
<thead>
<tr>
<th>Percent reporting hair regrowth</th>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rogaine after 8 months</td>
<td>10%</td>
<td>90%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

19% of women reported moderate hair regrowth after using Rogaine for 8 months. 19% had moderate regrowth; 40% had minimal regrowth. This compares with 7% of women reporting moderate hair regrowth after using the placebo, the liquid without minoxidil. After 8 months, 1% had moderate regrowth; 32% had minimal regrowth.

**What Minimal, Moderate and Dense Hair Regrowth Will Mean For You**

<table>
<thead>
<tr>
<th>Number of Hairs</th>
<th>Hair Density</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some hair areas are so thin that long new hairs do not grow close together as hairs on the rest of the head.</td>
<td>Hair density in thinning areas is reduced. New hairs grow more slowly together but are not as close together as hairs on the rest of the head.</td>
</tr>
<tr>
<td>New hairs cover some or all of thinning areas.</td>
<td>Hairs in thinning areas grow more slowly together at hair starts to close together as hairs on the rest of the head.</td>
</tr>
</tbody>
</table>

**Can Women's Rogaine be used to prevent hair loss?** We do not know if Rogaine will prevent hair loss.

**How soon can I expect results from using Women's Rogaine?** Since normal hair usually grows only 1/2 to 1 inch per month, hair regrowth with Rogaine also takes time. Generally new hair growth is slow for a Rogaine user. Continue use of 2 times a day for at least 4 months is usually needed before you notice hair regrowth.
If you do not see hair regrowth
in 4 months, stop using Rogaine
and see your doctor.

When you first begin to use
Rogaine, your hair loss may
continue for up to 2 weeks. This
hair loss is temporary. If you
continue to lose hair after two
weeks, see your doctor.

If Women's Rogaine is working,
what will the hair look like?
At first, hair growth may be soft,
downy, colorless hairs. After further
use, the new hairs should be the
same color and thickness as the
other hairs on your scalp.

How long do I need to use
Women's Rogaine?
If you respond to Rogaine,
you need to use it 2 times a day
to keep and continue the hair
regrowth. Up to 8 months of usage
can be needed to see your best
results from Rogaine.

What happens if I completely
stop using Women's Rogaine?
Continuous use of Rogaine is
needed to maintain hair regrowth.
If you stop using Rogaine, the
normal hair loss process will start
again. You will probably lose your
newly regrown hair in three to
four months.

What is the dosage of Women's
Rogaine?
You should apply a dose (1 mL) of
Rogaine directly onto the scalp
in the hair loss area TWO TIMES A
DAY; for example, once in the
morning and once at night. Each
cap should last about one month,
if used as directed. Please refer to
the "Directions for Use" section of
this booklet.

What if I miss a dose or forget
to use Women's Rogaine?
If you miss one or two daily doses
of Rogaine, just continue with
your next dose. You should not
make up for missed doses.

Can I use Women's Rogaine
more than two times a day? Will
it work faster, better?
No. Rogaine will not work faster
or better if used more than two
times a day. Studies by ProMace
have been carefully conducted to
determine the correct amount of
Rogaine needed to get the best
results. More frequent use or larger
doses have not been shown to
speed up hair growth and may
increase your chances of side
effects.

What are the most common
side effects with Women's
Rogaine?
The most common side effects
are itching and other skin irritations
of the treated area of the scalp.
Rogaine contains alcohol, which would cause burning or irritation of the eyes or sensitive skin areas. If Rogaine accidentally gets into these areas, rinse with large amounts of cool tap water. Contact your doctor if irritation persists.

What kind of shampoo should I use with Women's Rogaine? If you wash your scalp before applying Rogaine, use a mild shampoo.

Can I use hair sprays, mousses, conditioners, gels, etc.? Yes. There is no reason to change your usual hair care routine when using Rogaine. However, you should apply Rogaine first and work it in before any of your styling aids.

Can I have my hair colored or perm or use hair relaxers while using Women's Rogaine? Yes. We have no information that these treatments change the effect of Rogaine. However, to avoid possible scalp irritation, you should make sure all of the Rogaine has been washed off the hair and scalp before using these chemicals.

Can I apply Women's Rogaine and wash my hair an hour later? No. For Rogaine to work best, you should allow Rogaine to remain on the scalp for about 4 hours before washing.

Can I go swimming or out in the rain? Yes. Avoid washing off the Rogaine. If possible, apply Rogaine to a dry scalp after swimming, or wait about 4 hours after application before going swimming. Do not let your scalp get wet from the rain after applying Rogaine.

Can Women's Rogaine produce unwanted hair? Although unwanted hair growth has been reported on the face and on other parts of the body, such reports have been infrequent. The unwanted hair growth may be caused by the transfer of Rogaine to areas other than the scalp, or by absorption into the circulatory system of low levels of the active ingredient, or by a medical condition not related to the use of Rogaine.

If you experience unwanted hair, discontinue using Rogaine and see your doctor for recommendations about appropriate treatment. After stopping use of Rogaine, the unwanted hair, if caused by the use of Rogaine, should go away over time.
Can I use Women's Rogaine for baldness or hair loss in babies and children?
No. Rogaine must not be used to treat baldness or hair loss in babies or children.

Are there any special warnings about the use of Women's Rogaine?
For external use only
Flammable: Keep away from fire or flame
Do not use if
- your degree of hair loss is more than that shown on page 3 of this booklet, because this product may not work for you
- you have no family history of hair loss
- your hair loss is sudden and/or patchy
- your hair loss is associated with childbirth
- you do not know the reason for your hair loss

- you are under 18 years of age.
- Do not use on babies and children.
- your scalp is red, inflamed, infected, irritated, or painful
- you use other medicines on the scalp

Ask a doctor before use if you have heart disease.

When using this product
- do not apply on other parts of the body
- avoid contact with the eyes. In case of accidental contact, rinse eyes with large amounts of cool tap water.
- some people have experienced changes in hair color and/or texture
- it takes time to regrow hair. You may need to use this product 2 times a day for at least 4 months before you see results.
- the amount of hair regrowth is different for each person. This product will not work for everyone.

Stop use and ask a doctor if
- chest pain, rapid heartbeat, faintness, or dizziness occurs
- sudden, unexplained weight gain occurs
- your hands or feet swell
- scalp irritation or redness occurs
- unexplained facial hair growth occurs

Oxyntest Unit: 2586

Composition Unit: 1788

Composition Unit: 1788

Oxyntest Unit: 1788
• you do not see hair regrowth in 4 months

May be harmful if used when pregnant or breast-feeding. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

What factors may increase the risk of serious side effects with Rogaine?

Rogaine should be applied only to the scalp. The risk of side effects may be greater when Rogaine is applied to other parts of the body.

Directions for Use

1. Remove the overcap. To remove, line up arrows on bottle and overcap and pull off the overcap.
2. Remove the inner cap. To remove, push down and turn in direction of the arrows on the cap.
3. Part your hair in the area of hair thinning loss. Follow the instructions below for using the dropper applicator and apply one mL 2 times a day directly onto the scalp in the hair loss area. Do not use more. Spread the liquid evenly over the hair loss area. If you use your fingers, wash hands with soap and water immediately. Each bottle should last about one month, if used as directed. Use a mild shampoo if you wash your scalp before applying Rogaine.

Using the Dropper Applicator

1. Squeeze the rubber bulb and insert the dropper into the bottle.
2. Release the bulb, allowing the dropper to fill to the 1 mL line. If the level of the solution is above the 1 mL line, squeeze the extra amount back into the bottle.
3. Next, place the tip of the dropper near the part of the scalp you want to treat and gently squeeze the bulb to gradually release the solution. To prevent the solution from running off the scalp, apply a small amount at a time.
4. After each use attach the dropper to the bottle to make it child-resistant by turning it clockwise until tightly closed.
If you have any other questions, ask your health care professional or call us at 1-800-ROGAINE (1-800-764-2483). You can also visit our website at rogaine.com.

Store at Controlled Room Temperature 20° to 25° C (68° to 77° F).

Save this booklet for future reference.
APPLICATION NUMBER:
19-501/S025

MEDICAL REVIEW(S)
While cannot guarantee that it is the physician who personally responds to the survey, the Sponsor states that attempts to gear the process toward a personal response from the surveyed physician. The survey is personalized and mailed directly to each physician, and the physicians are asked which products and therapies they recommended to their patients. believes that, since such data is usually not charted, other office staff would have little insight as to the physician's verbal recommendations. To offset bogus responses to survey data, employs an editing process to exclude outliers or aberrations. The survey response rates have been consistent over time for each specialty group, indicating stable reporting trends.

The survey respondent receives a $5 honorarium with the option to donate this $5 to one of three charities: the American Cancer Society, the American Heart Association, or the Multiple Sclerosis Society. The offer of the small honorarium could probably not be said to rise to the level of influencing a physician’s product recommendation, however, the question of whether the survey is really completed by the named dermatologist and not by a member of his office staff is not easily answered, and probably can not be answered definitively.

There are other inherent flaws and weaknesses in the survey process and the survey instrument. The survey instrument does not mention any of the competing store brands or generic products by name. The only OTC products mentioned by brand name are the Rogaine products, and the only other product specifically mentioned by name is the prescription product, Propecia. This may lead the respondent to assign recommendations either more frequently or even exclusively to the three Rogaine products, rather than to unnamed competing OTC products which may not be as easily recalled. Another weakness is that most of the survey responses received each year come from solo or small group physician practices (66.61% in 2003), which does not reflect a broad cross section of the dermatologist population.

Nevertheless, even with the limitations and deficiencies mentioned above, based on the data for 2003 it is not entirely unreasonable for Pfizer to claim that Rogaine hair regrowth products are the “#1 Dermatologist Recommended Brand” using aggregate data. Results collected from 2,655 dermatologists in 2003 show that the dermatologists recommended Rogaine products an average of 9.79 times per week, compared with all non-Rogaine options combined (OTC and Rx) which were recommended an average of 4.20 times per week. When comparing just the OTC options, Rogaine products were recommended an average of 9.79 times per week, compared with store brands or generics that were recommended an average of 1.59 times per week. Note, however, that the claim “#1 Dermatologist Recommended Brand” does not hold true if applied just to the individual Men’s Regular Strength Rogaine (2% minoxidil) product, which actually had fewer dermatologist recommendations than Propecia.

### Average Weekly Recommendations Per Physician – National Survey Data from Fourth Quarter 2003

<table>
<thead>
<tr>
<th>Responders</th>
<th>Rogaine Women’s 2%</th>
<th>Rogaine Men’s 2%</th>
<th>Rogaine Men’s 5%</th>
<th>All Rogaine Combined</th>
<th>Store Brands/ Generics (Men’s)</th>
<th>Store Brands/ Generics (Women’s)</th>
<th>Propecia Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,655</td>
<td>3.37</td>
<td>1.75</td>
<td>4.67</td>
<td>9.79</td>
<td>0.93</td>
<td>0.66</td>
<td>2.61</td>
</tr>
</tbody>
</table>

The "#1 Dermatologist Recommended Brand" statement for Rogaine products is based on fairly typical, even though scientifically limited marketing-related survey data. Overall, data for 2003 indicate that Rogaine products received more recommendations, as a brand group, than store
brands or generic products, or the prescription therapy Propecia. On average, the dermatologists who responded to the survey recommended a Rogaine product 69.99% of the time, a generic product 11.35% of the time, and Propecia 18.65% of the time, indicating that those physicians made more recommendations for Rogaine products than for Propecia (Rx) or competing OTC store brands/generics. To ensure that the brand claim remains accurate, Pfizer has agreed to examine the quarterly collections of survey data and re-evaluate its claim every 12 months.

<table>
<thead>
<tr>
<th>Responders</th>
<th>Rogaine Women’s 2%</th>
<th>Rogaine Men’s 2%</th>
<th>Rogaine Men’s 5%</th>
<th>All Rogaine Combined</th>
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<th>Store Brands/ Generics (Women’s)</th>
<th>Propecia Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,655</td>
<td>24.10</td>
<td>12.51</td>
<td>33.38</td>
<td>69.99</td>
<td>6.62</td>
<td>4.73</td>
<td>18.65</td>
</tr>
</tbody>
</table>

Concerning the use of a seal on the front display panel, the Agency has suggested that the seal is misleading in that it suggests endorsement by a medical society. However, no such statement is made, and with the modified shape of the seal and the removal of the caduceus symbol, it is unlikely that consumers would reach that conclusion. A large number of consumer products on the market today, including many healthcare products, promote themselves with similar seals and statements on the product packaging. Given the proliferation of such seals in the marketplace, it is reasonable to conclude that consumers view these symbols as simply promotional in nature. The modified seal is indicated below.

In its response to FDA’s Approvable Letter dated 3/19/04, Pfizer points out that a number of consumer products on the market today promote themselves with brand leadership statements and use seals and emblems on product packaging. Several examples are listed below and are attached to this review (see Appendix). As can be seen, many of the seals and emblems continue to include the caduceus symbol, which Pfizer has actually removed from its own seal.

- Phazyme (for gas relief)
- Fleet (glycerin suppositories)
- Efamil (pediatric vitamin drops)
- St. Joseph (aspirin)
- Dulcolax (laxative)
- Feosol (iron supplement)
- Alcon (lubricant eye drops)
- Phillips (laxative and antacid)
- St. Joseph (aspirin)
- Tyril (laxative)
- Tylenol (bottle)
- Tavist (allergy/sinus/headache relief)
- Scalpicin (for seborrheic dermatitis)
- Curel (moisturizing lotion)
- Renu (multipurpose contact lens solution)
- Ecotrin (enteric aspirin)
- Chlortrimeton (antihistamine)
- Dimetapp (nasal decongestant/antihistamine)
- Triaminic (pediatric antihistamine/nasal decongestant)

**Recommendation:** Notwithstanding some inherent weaknesses in the marketing data, I would, at this time, approve the claim “#1 Dermatologist Recommended Brand,” and approve the revised seal for the principal display panel on the product packaging.

* Sponsor states that these were “statistically significantly more” and needs to supply the P-value to indicate significance.
Proposed packaging for Rogaine Regular Strength for Men (2% Unscented) and Rogaine 2% for Women (Scented and Unscented) with the revised seal and the "#1 Dermatologist Recommended Brand" claim.
BACKGROUND

Pfizer has submitted this supplement in support of the claim "#1 Dermatologist Recommended Brand" in labeling for Men’s Rogaine Regular Strength and Women’s Rogaine (2% Minoxidil Topical Solution) products (fragranced and unfragranced) covered by NDA 19-501.

Prior submissions, sNDA S-020, provided labeling for Men's Rogaine Regular Strength and Women's Rogaine (both without fragrance) in the Drug Facts format. That labeling was modified in an August 13, 2002 amendment, and an approvable letter was issued on February 3, 2003.

Supplemental NDA S-021 was submitted on December 2, 2002, which originally provided for a new child-resistant overcap, but the child-resistant overcap was retained. This supplement is at the approvable stage pursuant to the Agency's June 5, 2003 letter.

Supplemental NDA S-024 provided for the addition of a fragrance to Women's Rogaine as an alternate presentation. During the review of supplements S-020, S-021, and S-024, the Agency requested that the claims "#1 Dermatologist Recommended Brand" and "Dermatologist Recommended Brand" (within a "seal" graphic), be deleted from carton labeling pending the submission of satisfactory supporting data. In Pfizer's March 19, 2004 response to the approvable letter for supplement S-024, information was included to support the claim "Dermatologist Recommended Brand".

In a teleconference held with the Agency on June 3, 2004, FDA indicated that both of the above claims have essentially the same meaning (stated or implied), and direction was given to Pfizer as to additional background information that would be needed concerning the survey data submitted in support the claim. In order to facilitate the approval of supplement S-024 (which requested approval of the scented formula), Pfizer agreed to delete the above claim (pending submission of the additional requested data) and the approval letter was issued on June 25, 2004.

With regard to validating the "#1 Dermatologist Recommended Brand" claim, FDA asked Pfizer to submit a description of the survey method, including the following information:

- How were dermatologists selected and sampled?
- What was the response rate for dermatologists?
- Who completed the survey (e.g., physician, nurse, receptionist) and what assurance can be provided to prove that the dermatologists themselves completed the surveys?
- What monetary or other compensation did physicians receive for completing the survey?
- What questions were asked and in what order (i.e., what did the questionnaire look like)?
- What are the demographics (e.g., geographical location, academic/private/public institution, years in practice) of the survey participants?

FDA also told Pfizer to be aware that any data supporting the statement will have to be verified periodically in order to continue including the statement on the label. (See FDA “Minutes of a Teleconference” June 3, 2004).
RESPONSE TO FDA QUESTIONS ON THE SURVEY SUPPORTING THE 
#1 DERMATOLOGIST RECOMMENDED CLAIM

1. **How were dermatologists selected and sampled?**

The data used to support the claim “#1 Dermatologist Recommended Brand” is collected and processed by [redacted] which provides marketing data to numerous companies about dozens of product recommendations made by healthcare providers, and collects demographic data from a large number of potential prescribers/recommenders. [redacted] uses self-administered surveys circulated to more than 455,000 healthcare providers, in 55 healthcare specialties, in 30 therapeutic categories. The healthcare providers include 300,000 physicians, 150,000 dental healthcare providers and 20,000 physician assistants. Each physician receives the survey twice a year and the data is processed on a quarterly basis with a response rate of about 10-20%.

From this universe of prescribers, [redacted] surveys sub-populations by physician specialty. The basis of survey selection is to ensure that the response universe is similar to the real universe in terms of specialty and state. In other words, if Internal Medicine physicians represent 20% of all doctors in Arizona, the response universe should contain about 20% of Internal Medicine doctors. Within each specialty and state, the physicians with higher response probability are selected using a Logistic Regression model. In the model, all demographic data are used (location, gender, age, type of practice, historical response activity and so on).

2. **What was the response rate for dermatologists?**

The response rates for dermatologists in the last six quarters preceding the submission to FDA were:

- Q1 2003 - 28%
- Q2 2003 - 22%
- Q3 2003 - 22%
- Q4 2003 - 19%
- Q1 2004 - 22%
- Q2 2004 - 20%

3. **Who completes the survey (eg. physician, nurse, receptionist) and what assurance can be provided to prove that dermatologists themselves complete the survey?**

Although [redacted] can not guarantee that the physician (dermatologist) is personally responding to the survey, [redacted] believes that both the nature of its process and the survey encourage a personal response from the surveyed physician. Each [redacted] Physician Recommendation survey is personalized and mailed directly to each physician. The physician is asked to complete the survey and instructed on the honorarium check cashing and donation. The nature of questions on the [redacted] Recommendation Audit are related to medical practices exercised by the medical
professional, in this case, dermatologists. Physicians are asked what OTC therapies they recommended to their patients. \( (b)(4) \) believes that, since this data is generally not charted, other office staff would have little or no insight as to the physician's verbal recommendations. To offset bogus responses to survey data, \( (b)(4) \) employs an editing process to exclude outliers or aberrations. The survey response rates have been consistent over time for each specialty group, also indicating a stable reporting trend of specialty recommendations.

4. **What monetary or other compensation did physicians receive for completing the survey?**

The dermatologists receive a $5 honorarium with the option to donate this $5 to one of three charities: the American Cancer Society, the American Heart Association, or the Multiple Sclerosis Society.

The honorarium section of the survey is as follows.
5. What questions were asked and in what order (what did the questionnaire look like)?

The questionnaire asked the physicians to indicate the total number of times they recommend products listed in a variety of categories, not just hair growth products. The questionnaire asked the respondents to report any recommendation they make for non-brand-specific products (i.e., generics) under the heading Store Brands/Generics, and to skip products they do not recommend.

As mentioned earlier, there are some inherent weaknesses in the survey process and the survey instrument: (1) The survey instrument does not mention any of the competing store brands or generic products by name. This may lead respondents to assign recommendations more frequently or even exclusively to the three named Rogaine products, rather than to unnamed competing OTC products which may not be as easily recalled. (2) Most of the survey responses come from solo or small group physician practices (66.61% in 2003), which does not reflect a broad cross section of the dermatologist population. (3) There is absolutely no guarantee that it is the dermatologist who is completing the questionnaire rather than one of his/her office staff.

Listed on the following page is the Hair Growth Therapy category which included the items that yielded data for the “#1 Dermatologist Recommended” claim. Dermatologists were asked to indicate their weekly average frequency for recommending Rogaine versus generic and/or store brand OTC hair growth products, versus Propecia, which is the prescription hair growth product.
6. What are the demographics (e.g., geographical location, academic/private/public institution, years in practice) of the survey participants?

receives information on the universe of prescribers/recommenders from various associations including the American Medical Association. The AMA’s master list is used as the basis for the survey and includes all states, zip codes, age groups, medical specialties, and types of practices. The following table indicates the types of physician practices from which survey responses are received. These range from solo physician practices (44.51%), to group practices (22.10%), HMOs (0.42%), medical schools (1.64%), government hospitals and other medical facilities (1.95%), and private hospitals and clinics (7.17%).

**TABLE 1: TYPES OF PRACTICES**
also attempts to include physicians with a range of years of experience in its population. The number of years in practice ranged from one year or less to 66 years, with the highest percentage of respondents falling in the range of 20-40 years in practice.

TABLE 2: YEARS IN PRACTICE

The Survey Results

Definitions and Categories of Data Collected: Brand Management Reports have provided Average Weekly Recommendations per Physician and Brand Share data based on dermatologist recommendations for the Hair Growth Therapy category, on a quarterly basis, from 1998 through 2003, including the last 9 quarters.

Average Weekly Recommendations (AWR) per Physician is the value calculated by dividing the total weekly recommendations for a product or a category reported by the responder sample, by the number of physicians in the responder sample.

The Category is the combination of all products listed in the category. The Category Average Weekly Recommendations per Physician is the total of Average Weekly Recommendations of all products in the category.

The Brand Share (or Share Recommendations) is a product's percentage of the total Category's AWRs. It equals the sum of recommendations for a specific product in a category divided by the sum of the recommendations for all products in the category.

The Moving Annual Total (MAT) of AWR's/physician or Brand Share is based on the most recent rolling four quarters (i.e. Q403 MAT = Q403, Q303, Q203 and Q103).

Results from 2003: The data for 2003, collected from 2,655 dermatologists, shows that the dermatologists recommended a Rogaine product on average 9.79 times per week, a generic topical minoxidil product 1.59 times per week and Propecia (the Rx brand) 2.61 times per week.
### National Survey Data from Fourth Quarter 2003
#### Average Weekly Recommendations Per Physician

<table>
<thead>
<tr>
<th>Responders</th>
<th>Rogaine Women’s 2%</th>
<th>Rogaine Men’s 2%</th>
<th>Rogaine Men’s 5%</th>
<th>All Rogaine Combined</th>
<th>Store Brands/ Generics (Men’s)</th>
<th>Store Brands/ Generics (Women’s)</th>
<th>Propecia Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,655</td>
<td>3.37</td>
<td>1.75</td>
<td>4.67</td>
<td>9.79</td>
<td>0.93</td>
<td>0.66</td>
<td>2.61</td>
</tr>
</tbody>
</table>

A Brand Share calculation from this data indicates that, on average, dermatologists recommend a Rogaine product 69.99% of the time, a generic product 11.35% of the time, and Propecia 18.65% of the time, revealing that in 2003 there were more recommendations made by dermatologists for Rogaine than for Propecia (the prescription brand) which had the second highest number of recommendations in the Hair Growth Therapy category.

### National Survey Data from Fourth Quarter 2003
#### Brand Share of Hair Growth Therapies

<table>
<thead>
<tr>
<th>Responders</th>
<th>Rogaine Women’s 2%</th>
<th>Rogaine Men’s 2%</th>
<th>Rogaine Men’s 5%</th>
<th>All Rogaine Combined</th>
<th>Store Brands/ Generics (Men’s)</th>
<th>Store Brands/ Generics (Women’s)</th>
<th>Propecia Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,655</td>
<td>24.10</td>
<td>12.51</td>
<td>33.38</td>
<td>69.99</td>
<td>6.62</td>
<td>4.73</td>
<td>18.65</td>
</tr>
</tbody>
</table>

The Sponsor also included a histogram displaying data collected by showing Average Weekly Recommendations per office-based dermatologist for the year 2001. Although the information in this chart is out-of-date, it may be worth noting that Rogaine has been the most recommended brand among hair regrowth products since its OTC launch in 1996.

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* Sponsor states there were “statistically significantly more” and needs to supply the P-value to indicate significance.
The bar-graph shows that of the 2,410 dermatologists (out of an approximate total of 7,500 office-based dermatologists) who responded to the survey asking for their average weekly recommendations, Rogaine Extra Strength for Men was recommended on average 4.55 times per week; Women’s Rogaine (Regular Strength) was recommended 3.34 times on average per week; Men’s Regular Strength Rogain was recommended 1.98 times per week on average, and store/generic brands were recommended 0.66 and 0.60 times per week, on average, for men’s and women’s hair growth products respectively.

CONCLUSIONS

There are some inherent flaws and weaknesses in the survey process and the survey instrument. The survey instrument does not mention any of the competing store brands or generic products by name. The only OTC products mentioned by brand name are the Rogaine products, and the only other product specifically mentioned by name is the prescription product, Propecia. This may lead respondents to assign recommendations more frequently or even exclusively to the three Rogaine products, rather than to unnamed competing OTC products, which may not be as easily recalled. Another weakness is that most of the survey responses received each year come from solo or small group physician practices (66.61% in 2003), which does not reflect a broad cross section of the dermatologist population. Also, the question of whether the survey is really completed by the named dermatologist and not by a member of his office staff is not easily answered, and probably can not be answered definitively.

Nevertheless, even with the limitations and deficiencies mentioned above, based on the data for 2003 it is not entirely unreasonable for Pfizer to claim that Rogaine hair regrowth products are the “#1 Dermatologist Recommended Brand” using aggregate data. Results collected from 2,655 dermatologists in 2003 show that the dermatologists recommended Rogaine products an average of 9.79 times per week, compared with all non-Rogaine options combined (OTC and Rx) an average of 4.20 times per week. When comparing just the OTC options, Rogaine products were recommended an average of 9.79 times per week, compared with store brands or generics that received an average of 1.59 recommendations per week. Note, however, that the claim “#1 Dermatologist Recommended Brand” does not hold true if applied just to the individual Men’s Regular Strength Rogaine (2% minoxidil) product, which actually had fewer dermatologist recommendations, on average, than Propecia.

Concerning the use of a seal on the front display panel, the Agency has suggested that such a seal implies that the product is endorsed by a medical organization. However, no such statement is made, and with the modified shape of the seal and the removal of the caduceus symbol, it is unlikely that consumers would reach that conclusion. A large number of consumer products on the market today, including many healthcare products, promote themselves with similar seals and statements on the product packaging. Given the proliferation of such seals in the marketplace, it is reasonable to conclude that consumers view these seals as merely promotional in nature.

Recommendation: Notwithstanding some inherent weaknesses in the marketing data, I would, at this time, approve the claim “#1 Dermatologist Recommended Brand,” and approve the revised seal for the principal display panel on the product packaging.
### Attached Appendix: Examples of healthcare products that use seals, including seals with the caduceus symbol.

<table>
<thead>
<tr>
<th>Product</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phazyme (for gas relief)</td>
<td>Alcon (lubricant eye drops)</td>
</tr>
<tr>
<td>Curel (moisturizing lotion)</td>
<td>Fleet (glycerin suppositories)</td>
</tr>
<tr>
<td>Phillips (milk of magnesia laxative and antacid)</td>
<td>Renu (multipurpose contact lense solution)</td>
</tr>
<tr>
<td>Efamil (pediatric vitamin drops)</td>
<td>Dulcolax (laxative)</td>
</tr>
<tr>
<td>Ecotrin (enteric aspirin)</td>
<td>Scalpicin (seborrheic dermatitis anti-itch liquid)</td>
</tr>
<tr>
<td>St. Joseph (aspirin)</td>
<td>Tylenol (junior strength)</td>
</tr>
<tr>
<td>Chlortrimeton (anthistamine)</td>
<td>Triaminic (pediatric antihistamine &amp; nasal decongestant)</td>
</tr>
<tr>
<td>Dulcolax (laxative)</td>
<td>Tavist (allergy/sinus/headache relief)</td>
</tr>
<tr>
<td>Dimetapp (nasal decongestant &amp; antihistamine)</td>
<td>Feosol (iron supplement)</td>
</tr>
</tbody>
</table>
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/s/
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Susanna Weiss
6/2/05 04:35:52 PM
INTERDISCIPLINARY

Curtis Rosebraugh
6/3/05 07:19:56 AM
MEDICAL OFFICER
OTC Drug Labeling Review
for Men’s & Women’s Rogaine

Office of Nonprescription Products
Center for Drug Evaluation and Research • Food and Drug Administration
Rockville • MD 20857

SUBMISSION DATE(S): December 20, 2004
RECEIVED DATE(S): December 22, 2004

May 23, 2005
May 23, 2005

REVIEW DATE: June 7, 2005

NDA/SUBMISSION TYPE: NDA 19-501 (SLR025)

SPONSOR: Pfizer Consumer Healthcare

DRUG PRODUCT: Men’s & Women’s Rogaine

ACTIVE INGREDIENT: 2% minoxidil topical solution

PHARMACOLOGICAL CATEGORY: Hair regrowth treatment

STOCK KEEPING UNITS: submitted carton, bottle, & package insert labeling for 60 mL (2 fl oz) unscented men’s product & unscented & scented women’s products

REVIEWER: Matthew R. Holman, Ph.D.
BACKGROUND

On December 20, 2004, the sponsor submitted supplement SLR-025 to include a new “#1 dermatologist recommended” claim on the carton label for the following products:

- Men’s unscented Rogaine
- Women’s unscented Rogaine
- Women’s scented Rogaine

This submission responds to an approvable letter that FDA sent the sponsor on March 5, 2004, for S-024. The letter outlined the type of information necessary to support the claim.

REVIEWER’S COMMENTS

With the exception of adding the new “#1 dermatologist recommended” claim, the proposed labeling is identical to the last approved labeling, which was approved on June 25, 2004 (S-024). Pending the social scientist’s review of the information submitted to support this claim, the labeling is acceptable as proposed.

RECOMMENDATIONS

If the social scientist finds the submitted data and information sufficient to support the “#1 dermatologist recommended” claim, issue an approval letter for Men’s unscented regular strength Rogaine and Women’s unscented and scented regular strength Rogaine (2% minoxidil) and request final printing labeling.
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/s/
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Matthew Holman
6/6/05 03:02:43 PM
INTERDISCIPLINARY
APPLICATION NUMBER:
19-501/S025

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
MEMORANDUM OF TELECONFERENCE MEETING

DATE: June 20, 2005

APPLICATION NUMBERS: 1) sNDA 19-501/S-021
2) [Redacted]

BETWEEN:
Name: Dina Russello
Phone: 973-385-4909
Representing: Pfizer Consumer Healthcare

AND
Name: Tia Frazier
Division of Nonprescription Clinical Evaluation, HFD-560

SUBJECT: Ongoing regulatory issues related to sNDA 19-501/S-021 and sNDA 20-834/S-010

RE: sNDA 19-501/S-021:
Ms. Russello telephoned me at my request. I acknowledged Pfizer’s June 7, 2005 correspondence to S-025 requesting that FDA consolidate this supplement with application S-021. I first reviewed the changes proposed in S-021 with Ms. Russello, which are as follows: 1) new bottle and overcap modifications, and 2) changes to the product carton, label, and package insert. We reviewed the fact that Pfizer’s June 7, 2005, correspondence to application S-025 requests that we consider the information in that amendment, together with the contents of application S-025, as a complete response to application S-021. I explained that, to close S-021, Pfizer must instead submit a complete response to all of the deficiencies outlined in the June 5, 2003, approvable letter for that supplement in order to allow for a thorough review of the submitted information.
Ms. Russello verbalized understanding of the information that was conveyed on the telephone, and the conversation concluded cordially.

_____________________________
Tia Frazier, R.N., M.S.
Regulatory Project Manager
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/s/
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Tia Frazier
6/22/05 12:49:25 PM
CSO
June 7, 2005

Curtis Rosebraugh, M.D., Acting Director
Division of Nonprescription Clinical Evaluation (HFD-560)
Office of Nonprescription Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

Re: NDA 19-501/Amendment to S-025
Men’s Rogaine® Regular Strength/Women’s Rogaine® 2% Minoxidil Topical Solution

Subject: #1 Dermatologist Recommended Brand Claim
Consolidation with S-020 (Drug Facts)
Consolidation with S-021 (DRSF Overcap/Product Name/Labeling Changes)

Dear Dr. Rosebraugh:

In response to the telephone request made by Tia Frazier of your Division on May 31, 2005 for clarification regarding our request to consolidate supplements S-020 and S-021 with this supplement (S-025), the following information is provided.

Supplement S-020, dated March 22, 2002, was a CBE labeling supplement providing for adoption of the Drug Facts format for the Rogaine 2% products. Our amendment of August 13, 2002 responded to your approvable letter of July 12, 2002, and a second approvable letter was then issued on February 3, 2003. That letter (see Attachment #1) requested that the pregnancy warning read “May be harmful if used when pregnant or breast-feeding.” for both men’s and women’s products. At the time, these products were both unscented formulations. Subsequently, supplement S-024 was filed to add a fragrance to the women’s product as an alternate presentation. Labeling for that supplement was approved on June 25, 2004 with the pregnancy warning requested in your February 3, 2003 approvable letter for supplement S-020. Draft labeling implementing the same pregnancy warning in the men’s product and the unscented women’s product was later included in supplement S-025.

Hence, our request for consolidation of supplement S-020 into S-025 would complete the
Drug Facts approval for the remaining Rogaine 2% products with the new pregnancy warning.

Supplement S-021, dated December 2, 2002, was a CBE-30 supplement providing for changes in the bottle exterior and overcap configuration to meet child-resistant/senior-friendly (CR/SF) packaging requirements, and labeling changes which are detailed in the attached cover letter for that submission (see Attachment #2). In the Agency’s responding approvable letter, dated June 5, 2003 (see Attachment #3), several requests were made as follows:

1. 
2. 
3. Delete the claim, “DERMATOLOGIST RECOMMENDED BRAND” and the associated seal or provide supporting information.

The following point by point response to these items is offered as follows:

1. In the annual report for 2004, we informed the Agency 
2. 
3. Following discussions with the Agency, supplement S-025 was submitted on December 20, 2004 in support of a “#1 Dermatologist Recommended Brand” claim for use in labeling. This supplement is still under review.

Therefore, we repeat our request that supplements S-020 and S-021 be consolidated into your review of supplement S-025 for the sake of simplicity in resolving all open labeling issues for Rogaine 2% products.

This submission contains confidential/trade secret information to which all claims of privilege and confidentiality are asserted in both statutory and common law. Further dissemination may only be made with the express written permission of Pfizer Inc.
If there are any questions regarding this submission, please contact me at the telephone number below.

Sincerely,

Dina Russello
Director Regulatory Affairs
973-385-4909

Attachments
May 23, 2005

Central Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705

Attention: Charles Ganley, M.D., Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V

Re: NDA 19-501/S-025
Men’s Rogaine® Regular Strength and Women’s Rogaine 2% Minoxidil Topical Solution

Subject: Electronic Regulatory Submission for Archive
Labeling Supplement — “#1 Dermatologist Recommended Brand” Consolidation with Supplement S-020 and S-021

Dear Dr. Ganley:

Reference is made to the above noted labeling supplement (NDA 19-501/S-025) submitted on December 20, 2004 in support of the claim “#1 Dermatologist Recommended Brand” in labeling for Rogaine products (fragranced and unfragranced) covered by NDA 19-501.

Pursuant to Ms. Tia Frazier’s your request of May 19, 2005 for electronic copies of selected sections of this submission, enclosed please find the following items.

Item 1 Cover Letter
Item 2 PDP Labeling
Item 3 Pages 1-2 and Appendix 1 of Attachment 3
Item 4 Attachment 4 (excluding the cover letter)
Item 5 Attachment 5

These files were scanned with McAfee Virus Scan, Version 4.5.1 SP1, Virus Definition 4.0.4497, Scan Engine 4.4.00 and are virus free.
This submission contains confidential/trade secret information to which all claims of privilege and confidentiality are asserted in both statutory and common law. Further dissemination may only be made with the express written permission of Pfizer Inc.

Please call me at the number below should you have any questions concerning this submission.

Sincerely,

Dina R. Russello  
Director Regulatory Affairs  
(973) 385-4909
I write to request electronic copies of the selected sections of the NDAs below:

NDA 20-834 Supplement 009 dated 11/29/04
Cover letter, PDP, pages 1-2 and Appendix 1 of Attachment 3, contents of Attachment 4 excluding your company's 8/13/2002 letter, and the entire contents of attachment 5.

NDA 19-501 Supplement 025 dated 12/20/04
Cover letter, PDP, pages 1-2 and Appendix 1 of Attachment 3, Contents of Attachment 4 excluding your 8/15/2002 cover letter and the entire contents of attachment 5.

Receiving these items electronically (in editable format such as Word, if possible) will help expedite our review of these applications. If you are not able to send every item, simply send what you can. You may send these items in a CD or via e-mail directly to me as a review aid as long as you send an identical copy to the EDR.

Thank-you very much.
Tia Frazier, R.N., M.S.
Regulatory Project Manager
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Telephone: 301-827-2271
Fax: 301-827-2315
E-mail: fraziert@cdr.fda.gov
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Tia Frazier
5/20/05 09:13:36 AM
CSO
December 20, 2004

Charles Ganley, M.D., Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Blvd.
Rockville, MD 20850

Re:  NDA 19-501
Men's Rogaine® Regular Strength and Women’s Rogaine®
2% Minoxidil Topical Solution
Labeling Supplement

Subject:  “#1 Dermatologist Recommended Brand” Claim
Consolidation with Supplements S-020 and S-021

Dear Dr. Ganley:

This supplemental NDA is submitted in support of the claim “#1 Dermatologist Recommended Brand” in labeling for Rogaine products (fragranced and unfragranced) covered by NDA 19-501.

Please refer to sNDA S-020, which provided labeling for Men’s Rogaine Regular Strength and Women’s Rogaine (both without fragrance) in the Drug Facts format. That labeling was modified in our August 13, 2002 amendment, and an approvable letter was issued on February 3, 2003. Representative carton labels from this supplement are included in Attachment #1.

Supplemental NDA S-021 was submitted on December 2, 2002, which originally provided for a new child-resistant overcap. but the child-resistant overcap was retained. This supplement is at the approvable stage pursuant to the Agency’s June 5, 2003 letter.

Also, please refer to supplemental NDA S-024, which provided for the addition of a fragrance to Women’s Rogaine as an alternate presentation. During the review of supplements S-020, S-021, and S-024, the Agency requested that the claims “#1 Dermatologist Recommended Brand” and “Dermatologist Recommended Brand” (within a “seal” graphic), be deleted from carton labeling pending the submission of satisfactory supporting data. In Pfizer’s March 19, 2004 response to the approvable letter for supplement S-024, information was included to support the claim “Dermatologist Recommended Brand”. In a teleconference held with the Agency on June 3, 2004, FDA indicated that both of the above claims have essentially the same meaning (stated or implied), and direction was given as to the needed additional background information concerning the supporting survey (see FDA minutes

Pfizer Consumer Healthcare
Pfizer Inc
201 Tabor Road
Morris Plains, NJ 07950
Tel 973 385 2000

Consumer Healthcare
in Attachment #2. In order to facilitate the approval of supplement S-024, Pfizer agreed to delete the above claim and the approval letter was issued on June 25, 2004.

Background information for the “#1 Dermatologist Recommended Brand” claim requested by the Agency is contained in Attachment #3. For your convenience, survey results that were submitted in the August 13, 2002 correspondence and previously in March 19, 2004 correspondence are provided in Attachments #4 and #5, respectively. They were conducted in 2001 and 2003, respectively, and are consistent over time. To ensure the claim remains valid, however, we agree to revalidate it on an ongoing basis every 12 months.

Concerning the appearance of the “#1 Dermatologist Recommended Brand” claim and the Agency’s belief that the seal is misleading in that it suggests endorsement by a medical society, we agree to modify the shape of the seal and to delete the caduceus symbol.

Proposed draft artwork for representative cartons with the revised “#1 Dermatologist Recommended Brand” claim is enclosed in Attachment #6 for Men’s Rogaine Regular Strength (only available without fragrance), in Attachment #7 for Women’s Rogaine without fragrance, and in Attachment #8 for Women’s Rogaine with fragrance. These three attachments also contain all associated labeling components (bottle label, inner carton, and insert).

Currently, Men’s Rogaine Regular Strength and the unscented form of Women’s Rogaine are labeled in accordance with the approvable CBE sNDA S-021, and Women’s Rogaine with fragrance is labeled per the approved supplement S-024. The labeling in Attachments #6 through 8 is consistent with that covered by S-024 and incorporates all changes requested by the Agency in its review of supplements S-020 and S-021.

We request that the approvable supplements S-020 and S-021 be consolidated into this new supplemental NDA, which will then provide final approval for (1) Rogaine 2% products in Drug Facts format, (2) use of the new child-resistant overcap, and (3) the #1 Dermatologist Recommended Brand claim. The approval of this new supplement, together with the consolidation of supplements S-020 and S-021, will then close out all outstanding labeling issues for Rogaine 2% products.

Please contact me at the number below should you have any questions about this information.

Sincerely,

Dina Russello
Director, Regulatory Affairs
(973) 385-4909

Attachments