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Код по ОКПО 16417127
Р/с 40702810800030000627
в ОАО "МОСКОВСКИЙ КРЕДИТНЫЙ БАНК"
отделение "Спектр"
К/с 30101810300000000659
БИК 044585659

An Investigation Into The Efficacy of a Spider Vein Product

Kapel Reference No.: Spidervein.K0515-06

Date: May 15, 2006

Sponsor: DermaLabs
539 86th Street
Brooklyn, NY, USA

1.0 Objective

This panel has been convened to evaluate the efficacy if any of a product to reduce the appearance of spider veins.

2.0 Test Material

2.1 Test Sample Description:

On March 15, 2006 one sample labeled Spider Vein Treatment was received from DermaLabs and assigned Kapel Lab No. K0515-06.

2.2 Handling:

Upon arrival, the test material is assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date, and test requested.

Samples are retained for a period of three months beyond submission of final report unless other specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state, county, and local ordinances.

2.3 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, animal; toxicology, microbiology, or other in-vivo or in-vitro performance spectra will be required to assess the feasibility of commencement as dictated by an Institutional Review Board (IRB) described in section 3.0.

2.3.1 Sponsor purports that prior to sample submission the following tests were conducted with no adverse results and that the test data is on file at their premises and have not been made available to personnel:

- CTFA Preservative Efficacy Test or equivalent
- 90 Day Accelerated Stability and Container
- Compatibility Study

3.0 Institutional Review Board:

Reference: CFR Title 23, Part 56, Subparts A, B, C, and D.
The IRB consists of five or more individuals, chosen from within the company for technical expertise and from the local community for lay interaction. The list of IRB members is kept on file and is available for inspection during the hours of operation.

4.0 Panel Selection:

4.1 Standards for Inclusion in Study:

1) Individuals in generally good health and free of any systematic disorder which would interfere with the results, at the discretion of the Study Director.
2) Individuals who have completed a preliminary medical history and screening document as mandated.
3) Individuals who have read, understood, and signed an informed consent document as required by CFR Title 21, Part 50, Subpart B regulations. Consent forms are kept on file and are available for inspection on premises only during operational hours.
4) Individuals with no known abnormal response to cosmetic products and who are willing to cooperate with the study requirements.
5) Individuals who have spider veins.

4.2 Standards for Exclusion from Study:

1) Individuals who are under the care of a physician.
2) Individuals taking medication which in the opinion of the Study Director would mask or interfere with the results.
3) Individuals with known allergies or skin conditions which would interfere with the study at the discretion of the Study Director.
4) Individuals who are pregnant or lactating.
5) Individuals who are currently using any topical products which are intended to reduce spider veins.

4.3 Recruitment:

Panel selection is accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media, or any combination thereof.

4.4 Informed Consent Document:

An informed consent was obtained from each volunteer prior to initiating the study describing the reasons for the study, possible adverse effects, associated risks, and potential benefits of the treatment, and their limits of liability. Panelists signed and dated the informed consent document to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms are available for inspection on premises only. Reference 21 CFR Ch. 1 Part 50, Subpart B

5.0 Population Demographics:

Number of subjects enrolled:		25
Number of subjects completing study:		25
Age Range:		23-67
Sex:	Male:	1
	Female:	24
Race:	Caucasian:	20
	Hispanic:	4
	African American:	1

6.0 Methodology:

VivaScope 1500

The VivaScope 1500 system (Lucid) is a clinical confocal microscope used for imaging. The VivaCam Macro Camera which is a part of VivaScope, is intended to capture the surface level macroscopic images of skin and has a 24x magnification. Macroscopic images of the skin were taken using the VivaCam Macro Camera at hour 0, hour 1, day 1, and week 1, 2, and 4 of product usage.

7.0 Procedure:

Twenty-five healthy panelists with spider veins were recruited for this study. The demographic data is shown in Section 5.0.
The test material was weighed and distributed to the panelists.
Panelists were instructed to apply normal usage amounts of the test material to the designated area twice a day. Participants were also instructed to keep a daily log of usage noting date and time for each application together with any subjective comments.
Panelists were evaluated at 1 hour, 1 day, and week 1, 2, and 4. The technician scored any changes in appearance of spider veins.
Both technician and panelists scored the changes in spider veins using the following scale:

Significantly Improved: (Over 80-100% improved)
(Almost complete reduction in the red/blue coloring of spider veins)

Greatly Improved: (Over 60-80% improved)
(A significant reduction in the red/blue coloring of spider veins)

Improved: (Over 40-60% improved)
(Some reduction in the red/blue coloring of spider veins)

Somewhat Improved: (20-40% improved)
(A slight reduction in the red/blue coloring of spider veins)

Barely Improved: (10-20% improved)
(A bare noticeable reduction in the red/blue coloring of spider veins)

Same No Change

Not As Good

8.0 Results:

Please refer to the attached tables.

At 1 hour, the technician noted the following:
84% of the panel showed no change in appearance of spider veins.
16% of the panel showed a bare improvement in the appearance of spider veins.

At 1 hour, the panelist noted the following:
76% of the panel showed no change in the appearance of spider veins.
20% of the panel showed a bare improvement in the appearance of spider veins.
4% of the panel showed a somewhat improvement in the appearance of spider veins.

At day 1, the technician noted the following:
60% of the panel showed no change in the appearance of spider veins.
24% of the panel showed a bare improvement in the appearance of spider veins.
8% of the panel showed a somewhat improvement in the appearance of spider veins.
8% of the panel showed an improvement in the appearance of spider veins.

At day 1, the panelist noted the following:
52% of the panel showed no change in the appearance of spider veins.
36% of the panel showed a bare improvement in the appearance of spider veins.
12% of the panel showed a somewhat improvement in the appearance of spider veins.

At week 1, the technician noted the following:
44% of the panel showed no change in the appearance of spider veins.
44% of the panel showed a bare improvement in the appearance of spider veins.

4% of the panel showed a somewhat improvement in the appearance of spider veins.
8% of the panel showed an improvement in the appearance of spider veins.

At week 1, the panelist noted the following:
36% of the panel showed no change in the appearance of spider veins.
24% of the panel showed a bare improvement in the appearance of spider veins.
32% of the panel showed a somewhat improvement in the appearance of spider veins.
8% of the panel showed an improvement in the appearance of spider veins.

At week 2, the technician noted the following:
36% of the panel showed no change in the appearance of spider veins.
40% of the panel showed a bare improvement in the appearance of spider veins.
12% of the panel showed a somewhat improvement in the appearance of spider veins.
8% of the panel showed an improvement in the appearance of spider veins.
4% of the panel showed a great improvement in the appearance of spider veins.

At week 2, the panelist noted the following:
32% of the panel showed no change in the appearance of spider veins.
48% of the panel showed a bare improvement in the appearance of spider veins.
8% of the panel showed a somewhat improvement in the appearance of spider veins.
12% of the panel showed an improvement in the appearance of spider veins.

At week 4, the technician noted the following:
48% of the panel showed no change in the appearance of spider veins.
40% of the panel showed a bare improvement in the appearance of spider veins.
8% of the panel showed a somewhat improvement in the appearance of spider veins.
4% of the panel showed a not as good improvement in the appearance of spider veins.

At week 4, the panelist noted the following:
44% of the panel showed no change in the appearance of spider veins.
44% of the panel showed a bare improvement in the appearance of spider veins.
12% of the panel showed a somewhat improvement in the appearance of spider veins.

9.0 Objective

No adverse reactions of any kind were noted during the course of this study.

10.0 Archiving

All raw data sheets, technician's notebooks, correspondence files, and copies of final reports are maintained on premises in limited access storage files marked "Archive" for five years after completion of study. A duplicate disk copy of final reports is separately archived in a bank safe deposit vault.

10.0 Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, the test sample improved the appearance of spider veins.

Table 1

Clinical Grading
Technician

Kapel Reference No.: K0515-06
Product Name: Spider Vein Treatment

Panelist ID	1 Hour	Day 1	Week 1	Week 2	Week 4
05-6391	Barely Improved	Same No Change	Same No Change	Same No Change	Same No Change
05-6276	Same No Change	Somewhat Improved	Improved	Greatly Improved	Same No Change
05-6121	Same No Change	Same No Change	Same No Change	Barely Improved	Barely Improved
05-6755	Same No Change	Same No Change	Same No Change	Same No Change	Barely Improved
05-6700	Same No Change	Barely Improved	Barely Improved	Barely Improved	Barely Improved
05-6028	Same No Change	Same No Change	Same No Change	Same No Change	Not As Good
05-6100	Barely Improved	Improved	Improved	Somewhat Improved	Same No Change
05-6643	Same No Change	Barely Improved	Barely Improved	Barely Improved	Same No Change
05-6725	Barely Improved	Improved	Barely Improved	Barely Improved	Same No Change
05-6061	Barely Improved	Barely Improved	Barely Improved	Barely Improved	Same No Change
05-6034	Same No Change	Same No Change	Same No Change	Barely Improved	Somewhat Improved
05-6930	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6668	Same No Change	Barely Improved	Barely Improved	Barely Improved	Barely Improved
05-6161	Same No Change	Somewhat Improved	Barely Improved	Improved	Barely Improved
05-6536	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6145	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6146	Same No Change	Same No Change	Barely Improved	Somewhat Improved	Same No Change
05-6076	Same No Change	Same No Change	Barely Improved	Barely Improved	Barely Improved
05-6929	Same No Change	Same No Change	Same No Change	Same No Change	Barely Improved
05-6884	Same No Change	Barely Improved	Barely Improved	Improved	Somewhat Improved
05-6089	Same No Change	Same No Change	Barely Improved	Barely Improved	Same No Change
05-6526	Same No Change	Barely Improved	Barely Improved	Barely Improved	Barely Improved
05-6123	Same No Change	Same No Change	Same No Change	Same No Change	Barely Improved
05-6185	Same No Change	Same No Change	Somewhat Improved	Somewhat Improved	Same No Change
05-6947	Same No Change	Same No Change	Same No Change	Same No Change	Barely Improved

Table 2

Clinical Grading
Panelist

Kapel Reference No.: K0515-06
Product Name: Spider Vein Treatment

Panelist ID	1 Hour	Day 1	Week 1	Week 2	Week 4
05-6391	Barely Improved	Barely Improved	Barely Improved	Same No Change	Same No Change
05-6276	Barely Improved	Barely Improved	Somewhat Improved	Improved	Barely Improved
05-6121	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6755	Somewhat Improved	Somewhat Improved	Same No Change	Same No Change	Same No Change
05-6700	Same No Change	Same No Change	Improved	Barely Improved	Barely Improved
05-6028	Same No Change	Barely Improved	Barely Improved	Barely Improved	Same No Change
05-6100	Same No Change	Barely Improved	Somewhat Improved	Barely Improved	Same No Change
05-6643	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6725	Same No Change	Barely Improved	Somewhat Improved	Barely Improved	Barely Improved
05-6061	Same No Change	Somewhat Improved	Somewhat Improved	Somewhat Improved	Somewhat Improved
05-6034	Same No Change	Same No Change	Same No Change	Barely Improved	Barely Improved
05-6930	Same No Change	Same No Change	Same No Change	Barely Improved	Barely Improved
05-6668	Barely Improved	Barely Improved	Barely Improved	Barely Improved	Barely Improved
05-6161	Barely Improved	Barely Improved	Somewhat Improved	Somewhat Improved	Somewhat Improved
05-6536	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6145	Same No Change	Same No Change	Barely Improved	Barely Improved	Same No Change
05-6146	Same No Change	Same No Change	Barely Improved	Improved	Barely Improved
05-6076	Same No Change	Somewhat Improved	Somewhat Improved	Barely Improved	Barely Improved
05-6929	Same No Change	Barely Improved	Barely Improved	Barely Improved	Barely Improved
05-6884	Barely Improved	Barely Improved	Improved	Improved	Somewhat Improved
05-6089	Same No Change	Same No Change	Somewhat Improved	Barely Improved	Barely Improved
05-6526	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6123	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change
05-6185	Same No Change	Same No Change	Somewhat Improved	Barely Improved	Barely Improved
05-6947	Same No Change	Same No Change	Same No Change	Same No Change	Same No Change

Table 3

Technician Questionnaire
Summary Of Results

Kapel Reference No.: K0515-06
Product Name: Spider Vein Treatment

	How did the Spider Veins look after the use of the product?				
Grade	**1 Hour**	**Day 1**	**Week 1**	**Week 2**	**Week 4**
Same: No Change	21 (84%)	15 (60%)	11 (44%)	9 (36%)	12 (48%)
Barely Improved (10-20%)	4 (16%)	6 (24%)	11 (44%)	10 (40%)	10 (40%)
Somewhat Improved (20-40%)		2 (8%)	1(4%)	3 (12%)	2 (8%)
Improved (40-60%)		2 (8%)	2 (8%)	2 (8%)	
Greatly Improved (60-80%)				1 (4%)	
Significantly Improved (80-100%)					
Not As Good					1 (4%)
Overall % Agreement	16%	40%	56%	64%	52%

Note:

1) "Overall % Agreement" is expressed as the total percentage of subjects answering Barely Improved, Somewhat Improved, Greatly Improved, and Significantly Improved, divided by the number of subjects answering the questionnaire each week, multiplied by 100.
2) Data depicted in the Grade Column is the scale used to evaluate the product.

Table 4

Panelist Questionnaire
Summary Of Results

Kapel Reference No.: K0515-06
Product Name: Spider Vein Treatment

	How did the Spider Veins look after the use of the product?				
Grade	**1 Hour**	**Day 1**	**Week 1**	**Week 2**	**Week 4**
Same: No Change	19 (76%)	13 (52%)	9 (36%)	8 (32%)	11 (44%)
Barely Improved (10-20%)	5 (20%)	9 (36%)	6 (24%)	12 (48%)	11 (44%)
Somewhat Improved (20-40%)	1 (4%)	3 (12%)	8 (32%)	2 (8%)	3 (12%)
Improved (40-60%)			2 (8%)	3 (12%)	
Greatly Improved (60-80%)					
Significantly Improved (80-100%)					
Not As Good					
Overall % Agreement	24%	48%	64%	68%	56%

Note:

1) "Overall % Agreement" is expressed as the total percentage of subjects answering Barely Improved, Somewhat Improved, Greatly Improved, and Significantly Improved, divided by the number of subjects answering the questionnaire each week, multiplied by 100.
2) Data depicted in the Grade Column is the scale used to evaluate the product.

Table 5

Weight In Grams

Kapel Reference No.: K0515-06
Product Name: Spider Vein Treatment

Panelist ID	Pre-Weight	Post Weight	Diff. In Weight
05-6391	76.34	64.28	12.06
05-6276	77.85	49.77	28.06
05-6121	76.48	72.42	4.06
05-6755	79.81	55.58	24.23
05-6700	74.23	60.20	14.03
05-6028	75.00	70.86	4.14
05-6100	74.07	60.86	13.21
05-6643	76.68	52.90	23.78
05-6725	77.34	52.73	24.61
05-6061	77.12	60.57	16.55
05-6034	78.65	47.28	31.37
05-6930	77.19	61.33	15.86
05-6668	77.43	75.40	2.03
05-6161	78.59	63.71	14.88
05-6536	74.33	70.52	3.81
05-6145	75.78	65.29	10.49
05-6146	79.37	78.00	1.37
05-6076	77.35	42.88	34.47
05-6929	74.15	59.66	14.49
05-6884	75.34	30.27	45.07
05-6089	80.00	75.11	4.89
05-6526	75.68	71.55	4.13
05-6123	80.50	79.40	1.10
05-6185	79.80	76.36	3.44
05-6947	74.56	71.21	3.35