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AN INVESTIGATION INTO THE EFFICACY OF TOPICALLY APPLIED PRODUCT TO REDUCE THE APPEARANCE OF CELLULITE

AMA Ref. No.: MS07.INUSE.L0442.REP20.PSO.REV

Date: June 3, 2009

Sponsor: Pure Source, Inc.
9750 NW 17th Street
Miami, Florida 33172

1.0 Objective:

The purpose of this study is to evaluate the efficacy of a topically applied body cream product intended to reduce the appearance of cellulite after 2, 4, 6 and 8 weeks of use. Assessments were conducted visually, photographically and instrumentally. In addition efficacy and tolerance were evaluated using panelist questionnaire responses.

2.0 Sample Description:

On February 22, 2007 test samples labeled Body Shaping Cream, Lot # 10150F-15 were received from Pure Source, Inc. and assigned AMA Lab No. L-0442.

2.1 Test Material Evaluation Prerequisite:

Prior to induction of a human test panel, toxicology, microbiology or in-vitro performance spectra may be required to assess the feasibility of commencement as dictated by an Institutional Review Board (IRB) described in Section 4.4.

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

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

3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested.

Samples are retained for a period of three months beyond submission of final report unless otherwise 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 and local ordinances.

4.0 Population Demographics:

Number of subjects enrolled		20
Number of subjects completing study		20
Age Range		25 - 55
Sex	Male	0
	Female	20
Race	Caucasian	19
	Hispanic	1

4.1 Standards For Inclusion In a Study:

1. Individuals between the ages of 25 and 55.
2. Individuals in general good health and free of any dermatological or systemic disorder that would interfere with the results or increase the risks of study participation, at the discretion of the Investigator.
3. Individuals with no hair in test site areas that would interfere with instrumental readings.
4. Individuals who have completed a preliminary medical history and screening document mandated by AMA Laboratories, Inc.
5. Individuals who have read, understood and signed an informed consent document required by CFR Title 21, Part 50, Subpart B regulations.
6. Individuals able to cooperate with the Investigator and the research staff and are willing to complete the full course of the study.

7. Individuals who understand the instructions for use and are willing to cooperate with the program as stated.
8. Individuals with no known abnormal responses to topically applied products.
9. Individuals who have abstained from using any topical treatment products for a period of 72 hours prior to study commencement and during the test period.

4.2 Standards for Exclusion from a Study:

1. Individuals who are under the care of a physician.
2. Individuals who are currently taking any medication that may mask or interfere with the test results at the discretion of the Study Director.
3. Subjects with a history of any form of skin cancer, melanoma, lupus, psoriasis, connective tissue disease, diabetes or any disease that would increase risk associated with study participation.
4. Females who are pregnant, lactating, have been pregnant, or given birth within the six month period immediately preceding study commencement. Females who intend to become pregnant over the study period.
5. Individuals diagnosed with chronic skin allergies or with history of hypersensitivity to cosmetics in general.

4.3 Informed Consent and Medical History:

Prior to initiating the study, a signed informed consent was obtained, in accordance with CFR Title 21, Part 50, Subpart B, from each panelist, describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. 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 the premises of AMA Laboratories, Inc. only.

4.4 Recruitment:

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

4.5 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc., consists of five or more individuals,

chosen from within the company for technical expertise and also from the local community for lay interaction. The list of IRB members is kept on file at AMA Laboratories, Inc., and is available for inspection during the hours of operation.

5.0 Methodology:

Twenty healthy females between the ages of 25 and 55 were inducted into this study. The subjects were pre-qualified for participation by the Study Director based on the presence of visible cellulite in the thigh region. In order to pre-condition the test sites and keep all topical treatments consistent during the study, the panelists were required to abstain from using any moisturizers or topical treatment products, including lotions creams and gels, for a period of 72 hours prior to study commencement and to use only the assigned test material throughout the study period.

All participants were instructed to use the test material for eight weeks according to the following sponsor supplied directions:

USE INSTRUCTIONS:

Apply product ad-libitum, two times daily.

Participants were provided with a daily log and instructed to record the time of each application together with any subjective comments regarding product usage. Visual assessments and biophysical measurements were collected prior to the initial application during the preliminary visit to the testing facility and again after 2, 4, 6 and 8 weeks of use. On the evaluation days, panelists reported to the clinic without any topical treatments, having only applied the test material. Upon arrival, panelists were allowed to equilibrate to the ambient environment for 30 minutes prior to measurement.

The following distinct noninvasive methods were employed as evaluation parameters:

Cellulite Reduction

Quantification of the cellulite condition was performed by a trained technician, using a modified and expanded version of the Fitzpatrick Wrinkle Evaluation Scale (ten point monadic scale), with one (1) representing the least visible discoloration and ten (10) showing the maximum condition in the region selected. Each woman had her condition evaluated, graded and separately photographed, by a scientific photographer, prior to the product being applied. The product was then applied in accordance with the intended package directions over an 8 week consumer in-use regimen

The modified and expanded 10-point monadic scaling method allows for the quantification and measurements of efficacy and is expressed as a percentage of cellulite reduction for each subject.

The photographs of each woman's selected cellulite region were placed side-by-side to compare the pre-treated area with the post-treated area. The set of photographs thus provided a visual record of the efficacy of the product.

All technical employees of AMA Laboratories, Inc. are required to take and pass a visual discrimination examination conducted by a Board Certified Ophthalmologist using the Farnsworth-Munsell 100 Hue Test as published; which determines a person's ability to discern color against a black background. This test was additionally modified to include a flesh tone background more nearly approaching actual use conditions, wherein erythematous skin is graded according to intensity.

Surface Evaluation of Living Skin (SELS) – Visioscan

The Visioscan (Courage and Khazaka) takes a direct image of the living skin using a measuring head containing a CCD-camera and two metal halogen lamps positioned opposite each other in order to ensure even illumination of the measuring field on the skin. The grey level distribution of the pixels in the image correspond to different phenomena (white pixels represent desquamation on the skin, dark pixels represent lines and indentations). Through special software (SELS – Surface Evaluation of Living Skin) the parameter of surface roughness (SEr) was evaluated in relative units for the most visible cellulite regions of the thigh.

Subjects were also asked to return to testing facility, with diary and complete a self assessment questionnaire after 2, 4, 6 and 8 weeks of treatment.

6.0 References:

1) Fitzpatrick, R.E., Goldman, M.P., and Tope, W.D., Pulsed carbon dioxide resurfacing of photo-aged facial skin, Arch. Dermatol., 132 (1996) 395-402.

2) Fischer, T.W., Wigger-Alberti W., Elsner P., Direct and non- direct measurement techniques for analysis of skin surface topography. *Skin Pharmacol Appl Skin Physiol 1999; 12:1-11.*

7.0 Statistical Source Data:

The source data are: Visual scoring, Questionnaire responses, Visioscan and Thigh measurements taken prior to application and again after 2, 4, 6 and 8 weeks of use. The data used in the statistical analysis reflect changes from baseline.

8.0 Results: Please refer to the attached Tables and Charts.

9.0 Observations:

No adverse effects or unexpected reactions of any kind were observed on any of the subjects.

10.0 Archiving:

All original samples, raw data sheets, technician's notebooks, correspondence files, copies of final reports and remaining specimens are maintained on the premises of AMA Laboratories, Inc. in limited access marked storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.

11.0 Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, twice daily use of the test product (AMA Lab No.: L-0442; Client No.: Body Shaping Cream, Lot # 10150F-15) demonstrated:

Visual Reductions in Cellulite

- Decreased appearance of cellulite at evaluations conducted after two, four, six and eight weeks of application. The following data collected on five subjects was observed in the treatment areas:

	2 weeks	4 Weeks	6 Weeks	8 Weeks
Mean % Difference	**-15.1%***	**-24.4%***	**-39.5%***	**-51.2%***

* Statistically Significant

When used in accordance with intended package directions, the product significantly reduced the appearance of cellulite after just two weeks of treatment. Continued reduction in the condition was observed after 4, 6 and 8 weeks of use with a maximum reduction of 90% observed. Additionally, the data is statistically significant.

Further, these phenomena were documented and confirmed by the photographic record made during the course of this study.

Evaluations of Surface Roughness via Visioscan

- Decreases in the Visioscan parameters associated with surface roughness (SEr) were also observed. Moreover, these reductions are considered statistically significant after 2 and 8 week's use with a maximum reduction of 72.9% observed.

	2 weeks	4 Weeks	6 Weeks	8 Weeks
Mean % Difference	**-17.3%***	**-22.0%**	**-28.3%**	**-33.5%***

* Statistically Significant

Questionnaire Responses

- Subjective responses (tabulated below) corroborated the visual data collected. Throughout the test period, the majority of test panelists perceived improvement in their skin for the conditions listed.

% Positive Responders

	2 Week	4 Weeks	6 Weeks	8 Weeks
Marked Improvement in the look of skin firmness in the thigh area	50%	65%	75%	85%
Skin feels significantly firmer	30%	60%	65%	75%
Skin feels significantly tighter	25%	65%	65%	80%
Skin feels significantly toned and lifted	30%	45%	70%	70%
Diminishes skin looseness and bagginess	30%	65%	70%	80%
Improves skin elasticity	35%	65%	65%	75%
Improves overall appearance	40%	70%	80%	85%
Improves overall health	55%	80%	90%	90%

Summation:

Twice daily use of the test product (AMA Lab No.: L-0442; Client No.: Body Shaping Cream, Lot # 10150F-15) reduced the appearance of cellulite. The results are considered statistically significant and were corroborated photographically, instrumentally and subjectively.

Signature Page

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9750 NW 17th Street
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Sample Description	AMA Lab No.
Body Shaping Cream, Lot # 10150F-15	L-0442

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Table 1
Visual Reduction – Cellulite Visual Scoring

AMA Lab No.: L-0442 Client No.: Body Shaping Cream, Lot # 10150F-15

Panelist ID	Baseline	2 Weeks	4 Weeks	6 Weeks	8 Weeks	Max. % Δ
46 3934	8	6	4	3	2	-75.00%
52 3942	6	5	3	3	3	-50.00%
60 3135	7	7	5	4	3	-57.10%
64 8003	8	7	7	7	5	-37.50%
82 1738	9	7	6	5	4	-55.60%
46-7887	8	7	5	3	2	-75.00%
48-2207	10	7	4	3	1	-90.00%
48-5321	9	7	6	4	2	-77.77%
50-1729	9	8	7	7	6	-33.33%
50-6005	9	8	8	8	8	-11.11%
52-7818	9	8	6	5	3	-66.66%
56-0317	9	8	7	5	5	-44.44%
56-4962	9	8	6	6	5	-44.44%
56-5529	9	8	8	7	7	-22.22%
60-7412	8	7	5	5	4	-50.00%
68-4950	8	6	5	3	2	-75.00%
72-2318	9	8	7	5	3	-66.66%
76-2719	10	8	7	7	7	-30.00%
82-6379	8	7	6	6	4	-50.00%
90-5388	10	9	9	8	8	-20.00%
Mean	**8.6**	**7.3**	**6.1**	**5.2**	**4.2**	
% Difference		**-15.12%**	**-24.42%**	**-39.53%**	**-51.16%**	
t		**8.84***	**9.57***	**9.90***	**10.05***	
p		**0.00***	**0.00***	**0.00***	**0.00***	

* Statistically Significant

Chart 1
Visual Reduction – Cellulite Visual Scoring

AMA Lab No.: L-0442 Client No.: Body Shaping Cream, Lot # 10150F-15

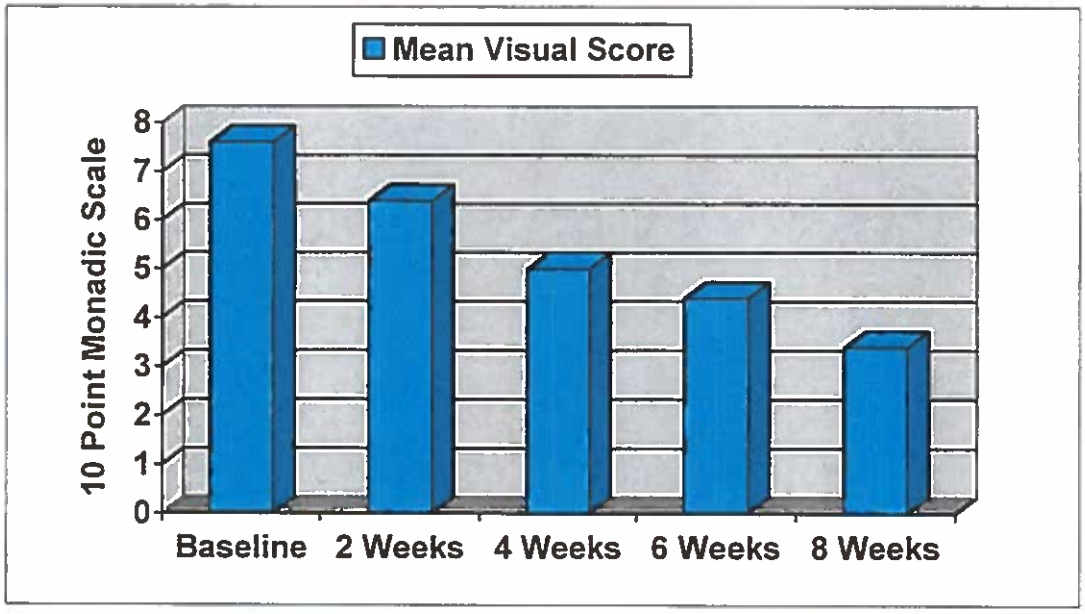

Table 2
Reduction in Surface Roughness – Visioscan Results

AMA Lab No.: L-0442 Client No.: Body Shaping Cream, Lot # 10150F-15

Visioscan – Surface Roughness (SEr)

Panelist ID	Baseline	2 Weeks	4 Weeks	6 Weeks	8 Weeks	Max. % Δ
46 3934	2.95	1.72	1.37	1.01	0.80	-72.9%
52 3942	3.88	3.26	3.74	3.58	1.86	-52.1%
60 3135	2.80	1.76	2.15	1.65	2.04	-41.1%
64 8003	1.49	1.40	1.39	1.30	1.27	-14.8%
82 1738	1.82	1.32	1.51	1.21	1.26	-33.5%
46 7887	1.77	1.40	1.38	1.17	1.28	-27.68%
48 2207	2.23	2.19	1.81	1.45	.86	-61.43%
48 5321	1.37	1.31	1.16	1.19	1.21	-11.68%
50 1729	1.65	1.44	1.67	1.25	1.36	-17.58%
50 6005	2.16	1.78	1.50	1.57	1.68	-22.22%
52 7818	1.29	1.16	.94	.80	.88	-31.78%
56 0317	1.32	1.28	1.22	.99	.98	-25.76%
56 4962	1.45	1.79	1.05	1.28	1.02	-29.66%
56 5529	1.62	1.32	1.31	1.32	1.10	-32.10%
60 7412	1.52	1.36	1.29	1.10	1.14	-25.00%
68 2561	1.57	.83	.99	.87	.94	-40.13%
72 2318	1.59	1.10	1.35	1.65	1.37	-13.84%
76 2719	2.22	2.88	1.29	1.73	1.74	-21.62%
82 6379	1.70	.99	1.57	.93	.64	-62.35%
90 5338	1.87	1.26	1.20	1.31	1.30	-30.48%
Mean	**1.91**	**1.58**	**1.49**	**1.37**	**1.27**	
% Difference		**-17.3%**	**-22.0%**	**-28.3%**	**-33.5%**	
t		**3.42***	**5.16***	**5.74***	**5.41***	
p		**0.00***	**0.00***	**0.00***	**0.00***	

* Statistically Significant