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AN INVESTIGATION INTO THE EFFICACY OF TOPICALLY APPLIED PRODUCT TO REDUCE THE APPEARANCE OF CELLULITE IN 42 DAYS

AMA Ref. No.: MS08.INUSE.L3111.REP2.GKL

Sponsor: Greek Island Labs, LLC
Adonia Organics LLC
Scottsdale, Arizona

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 and 6 weeks of use. Assessments were conducted visually and photographically.

Standards For Inclusion In a Study:

1. Individuals between the ages of 35 and 60.
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.

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.

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.

Methodology:

Females between the ages of 26 and 57 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.

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 and 6 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 method was employed as evaluation parameter:

Cellulite Reduction

Quantification of the cellulite condition was performed by a trained technician, using a modified and expanded version of the Fitzpatrick 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 6 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.

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.

Statistical Source Data:

The source data are: Visual scoring taken prior to application and again after 2, 4, and 6 weeks of use and submitted for review. The data used in the statistical analysis reflect changes from baseline.

Observations:

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

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-3111; Client No.: Adonia Leg Tone Serum) when used in accordance with intended package directions in 42 days demonstrated reductions in the appearance of cellulite with a maximum of 71.4% improvement. Decreases in thigh circumferences of approximately 0.6 inches were also noted. Further, this phenomenon was documented and confirmed during the course of the study.