AMA LABORATORIES, INC.
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21 DAY IMAGE ANALYSIS AND INVESTIGATION INTO THE EFFICACY OF A HAIR REDUCING PRODUCT FOR FACE AND BODY

AMA Ref. No.: MS10.INUSE.REP.L7434.GKL

Date: April 20, 2011

Sponsor: Greek Island Labs
Scottsdale, Arizona 33172

Objective:

This study was conducted to evaluate the efficacy of a product intended to reduce hair density. The effectiveness of the test product was evaluated via expert grading performed by the Trained Clinical Evaluator.

Standards for Inclusion in a Study:

a. Female subjects, between the ages of 18 and 55.
b. Individuals in normal health condition with no evidence of acute or chronic diseases, not having any known allergy to cosmetic products.
c. Individuals willing to report to the test facility with shaved legs (caves).
d. Individuals who completed a preliminary medical history form mandated by AMA Laboratories, Inc.
e. Individuals, who read, understood and signed an informed consent document relating to the specific type of study to which they are subscribing. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc. only.
f. Individuals willing to cooperate with the Investigator comply with protocol and complete the full course of the study.
g. Individuals who have abstained from shaving or depilating their legs or using any hair removal product or procedure on the test site for the duration of the study (21 days).

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 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.

Procedure:

Five healthy females between the ages of 25 and 53 were included into this study. On the initial day of the study panelists were required to report to the test facility with shaved legs (caves) and were allowed to equilibrate to the ambient environment for a 30 minute period. Each woman had her legs (calves) evaluated and photographed.

After the Baseline photographs were taken all panelists were dismissed with the instruction to apply the test product to the designated test site according to the following instructions:

Apply twice daily, once in the morning (or immediate after shaving) and once before bedtime). Do not apply any sunscreen or other creams, lotions on top of product.

After 21 days of use 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 their pictures be taken.

Detailed, high resolution matched digital photographs were taken prior to the initial application during the preliminary visit to the testing facility and again after 21 day of use. Photographs were taken with fixed camera background, distances, angles, settings, lighting, panelist positioning, color bars, white balance, standardized and digitally certified unretouched. Each stage in the progression of the test product regimen was photographically documented and the test area of involvement isolated. This set of photographs thus provided a visual record of the efficacy of the product.

At the study completion the Trained Clinical Evaluator (Expert Grader) graded the Baseline and Day 21 photographs of subjects' legs (calves) area for degree of hair density employing the 11-point intensity visual grading scale.

The Visual Analog Scale allows the Trained Clinical Evaluator (Expert Grader) to grade the subjects' hair density using the 11-point intensity grading scale where the severity of condition is ranked as follows: 0=no hair at all; 5=moderately dense hair; 10= extremely dense hair.

Hair Density Visual Grading Scale										
0	1	2	3	4	5	6	7	8	9	10
No hair at all				Moderately dense hair				Extremely dense hair		

Clinical Findings:

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

Observations:

No unexpected adverse reactions were observed on any of the subjects during the course of this study.

Statistical Source Data:

Hair density source data consists of Trained Clinical Evaluator photographs grades which were totaled and reported as average scores. The data used in the statistical analysis reflects changes from baseline.

Conclusions:

According to the study described herein, it can be demonstrated that Adonia Hair Reducer (AMA Lab No.: L-7434) proved to be effective at reducing the appearance of hair.

After 21 days of use the test product reduced hair appearance by an average of 46%.

Further, this phenomenon was documented and confirmed by the photographic record made during the course of this clinical study.

Mayya Tatsene, M.D.
Study Director

Jason Berke, A.A.S. Candidate
Photo Technician

David R. Winne, B.S.
Technical Director

4/20/11
Date

Quality Assurance Statement:

This study was inspected in accordance with the Standard Operating Procedures of AMA Laboratories, Inc. To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the study records and report.

Report reviewed by:

Kamil Wojtowicz, M.S.
Quality Assurance Supervisor

4/20/11
Date