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AN INVESTIGATION INTO THE EFFICACY OF A WRINKLE TREATMENT PRODUCT

AMA Ref. No.: MS05.WRPS.K8120.GKl

Date: November 7, 2005

Objective:

This study was conducted to evaluate the efficacy of a topically applied product intended to reduce the appearance of fine lines and facial wrinkles. Efficacy was evaluated visually and photographically for each subject prior to and following a single application of the test material.

Panel Selection:

Standards for Inclusion in a Study:

1. Individuals between the ages of 35 and 65.
2. Individuals not taking medication or under the care of a physician for a period of one month prior to commencement and throughout the entire test period.
3. Individuals who have completed a preliminary medical history mandated by AMA Laboratories, Inc.
4. Individuals, who have read, understood and signed an informed consent document as required by CFR 21, Part 50, and Subpart B Section 50.20 50.27. Consent forms are kept on file and are available for examination on the premises of AMA Laboratories, Inc., only.
5. Individuals who understand the instructions for use and are willing to cooperate with the program as stated.
6. Individuals free of any dermatological or systemic disorder that would interfere with the results, at the discretion of the Investigator.
7. Individuals able to cooperate with the Investigator and the research staff and are willing to complete the full course of the study.
8. Individuals who have abstained from using any wrinkle treatment products for a period of 72 hours prior to study commencement and during the test period.

Procedure:

The method employed for this study involved the selection of women, ranging in age from 41 to 50 years. The subjects were pre-qualified for participation on the basis of the presence of fine lines and wrinkles in the area around their eyes. In order to pre-condition the test sites and keep all topical treatments constant for all test subjects, panelists were required to abstain from using any wrinkle cream/gel products for a period of 72 hours prior to study commencement and during the test period.

For the purpose of this study, the wrinkles were defined as any small ridges and/or furrows formed on the surface of the skin, specifically, in the area around the eyes. These wrinkles, as such, were clearly visible to the unaided eye and were of sufficient depth and degree as to be commonly recognized on a woman's face in the "crow's feet" region around the eyes.

Quantification of the wrinkle condition was performed by the Study Director, employing a ten point monadic scale, with one (1) representing the fewest, least prominent fine lines and wrinkles and ten (10) showing the maximum number of deep fine lines and wrinkles. Each woman had her face evaluated, graded and separately photographed, by a scientific photographer, prior to the product being applied (Table 1, see attached). The product was then applied in accordance with the intended package directions.
A seven-minute period was permitted to elapse between

application and evaluation to allow the product to dry and assure consistent conditions between each subject. The subject's face was then re-evaluated by study director using the same 10-point monadic scale and photographed.

The photographs of each woman's face were then placed side-by-side so as to compare the pre-treated side of her face with the post-treated side. This set of photographs thus provided a visual record of the efficacy of the product, on the subjects face.

Results:

The use of the expanded Fitzpatrick Wrinkle Evaluation scaling method allows for the measurement and quantification of the efficacy of the product. This is expressed as a percentage of wrinkle reduction for each subject.

Clinical Findings:

No adverse effects or unexpected reactions of any kind were observed on any of the subjects. After seven minutes there was a significant observable decrease in the appearance of wrinkles in the area around the eyes of all subjects following the use of the product. The decrease is expressed as percentage difference between pre and post treatment ranging up to 90%.

Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, it can be demonstrated that the test material (AMA Lab No. K-8120, Client No. Athena 7-Minutes Lift) is effective for the reduction of fine lines and facial wrinkles. When used in accordance with intended package directions, the product in seven minutes significantly reduced the appearance of fine lines and facial wrinkles an average of 83.72% on a full face evaluation. Maximum reductions of 90% were observed. Additionally, the data is statistically significant.

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

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