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AN INVESTIGATION INTO THE EFFICACY OF A TEST MATERIAL INTENDED TO REDUCE HYPERPIGMENTATION ON THE FACE

AMA Ref. No.: MS13.CHROMA.M8931.REP.20.CRM

Date: July 24, 2014

Sponsor: Corum, Inc.
6F, No. 360, Ruei Guang Road
Neihu, Taipei, 11492
Taiwan

1.0 Objective:

This panel has been convened to evaluate the effectiveness of a topically applied test material intended to reduce hyperpigmentation on the face. The quantification of skin color changes associated with the use of the test material was evaluated via Minolta Chromameter Color Computer System.

2.0 Test Material:

2.1 Test Sample Description:

On February 25, 2013 test samples labeled CORUM, Whitening Spot Corrector (121127H) were received from Corum, Inc. and assigned AMA Lab No.: M-8931. For the purpose of this study additional samples received on May 1, 2014 were used.

2.2 Handling:

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

2.3 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 3.0.

2.3.1 Sponsor purports that prior to sample submission to AMA the samples were received and approved by the Sponsor's Safety Group for inclusion in this protocol.

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
- Fifty (50) person Repeat Insult Patch Test (RIPT) or equivalent

3.0 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C, and D. The IRB of AMA Laboratories, Inc. consists of 5 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.

4.0 Panel Selection:

4.1 Standards for Inclusion in a Study:

a. Individuals between 25 and 50 years old (average 32-37), exhibiting the visible hyperpigmented areas on the face (as determined by the Trained Evaluator).
b. Individuals who will complete a preliminary medical history and screening document as mandated by AMA Laboratories, Inc.
c. Individuals, who will read, understand and sign an informed consent document as required by CFR Title 21, Part 50, Subpart B regulations. Consent forms will be kept on file and are available for examination on the premises of AMA Laboratories, Inc., only.
d. Individuals in general good health and free of any health problems, including neurological, dermatological, or systemic disorder that in the opinion of the Study Director would make study participation inappropriate.

e. Individuals who will abstain from shaving or waxing the test site at least 72 hours prior to test commencement and throughout the study.
f. Individuals able to cooperate with the Investigator and research staff, willing to have the test material(s) applied according to the protocol, and complete the full course of study.
g. Individuals who are willing to abstain from use of any skin lightening/brightening products for at least 8 weeks prior to study commencement and use only the assigned test material for the duration of the study.
h. Individuals who regularly use sunscreens and who are willing to refrain from sunbathing or tanning bed use for at least 1 month prior to study initiation and the entire duration of the study.

4.2 Standards for Exclusion from a Study:

a. Subjects exhibiting rashes, scratches, birth marks etc., which might interfere with the evaluation of test results.
b. Female volunteers who indicate that they are pregnant or lactating.
c. Individuals who are under the care of a doctor.
d. Individuals with active dermal lesions, warts, nevi, and moles on the test site observed at the time of evaluation.
e. Individuals with known hypersensitivity to cosmetic products.
f. Individuals who were taking any antibiotics, antihistamines, retinoid, anti-inflammatory or steroid therapy for two weeks prior to or during the study period.
g. Individuals who were using systemic or topical medication for two weeks prior to or during the study period.
h. Individuals who have undergone whitening treatment procedures on the testing area within 1 month prior to study start.
i. Individuals who are participating in another study during the period of this study or who have participated in any other study within 1 month prior to this study.

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 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 and screening form. These forms, along with the signed consent forms, are available for inspection on the premises of AMA Laboratories, Inc., only. Reference 21 CFR Ch.1 Part 50, Subpart B.

5.0 Panel Demographics:

Number of subjects enrolled		20
Number of subjects completing study		20
Age Range		25 - 50
Sex	Female	20
Race	Caucasian	12
	Hispanic	2
	Asian	6

6.0 Procedure:

Twenty healthy females were inducted into this study. The demographic data is shown in Section 5.0.

As a condition of enrollment, subjects were instructed to abstain from using of any lightening/brightening products 8 weeks prior to study commencement. On the initial day of the study, upon arrival at the testing facility, subjects were required to familiarize themselves with and sign the informed consent. Subjects were mandated to adhere to all the restrictions mentioned in the inclusion/exclusion section (refer to 4.1 and 4.2). All participants were advised of the general nature and purpose of this study.

On the initial day of the study each panelist had her face evaluated by a trained technician in order to determine the presence of the test article (areas of hyperpigmentation on the face).

All study panelists were instructed to use the test product as part of their daily routine according to the following sponsor supplied instructions:

Apply suitable amount of test product onto the entire face twice a day after cleansing the face.

On each evaluation day (Baseline, Day 14, 28 and Day 56) panelists reported with the test site devoid of any topical treatments and were examined by a trained technician. Panelists were allowed to equilibrate to the ambient environment for 30 minutes prior to measurements.

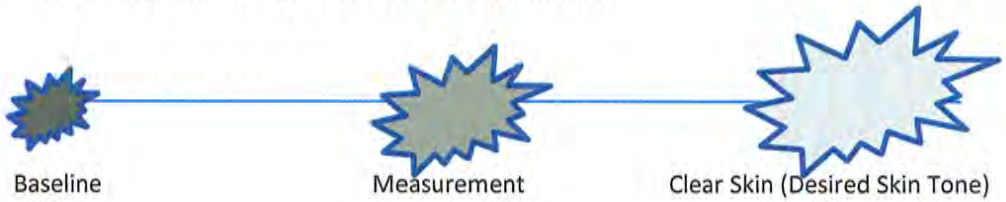
The following distinct noninvasive method was employed to establish evaluation parameter:

Skin Color Brightness/ Lightness (L*) - Minolta Chromameter

The Minolta CR-200 Chromameter detects subtle changes in color by a three dimensional profile of hue, value and chroma. These characteristics are then translated into color coordinates (a*, b* and L*) whose spacing is considered to correlate with the color changes perceived by the human eye. Any increase in the L* coordinate indicates lightening of the color. Any diminution of the L* coordinate is indicative of the darkening of color.

	L* Coordinate
Increase	Lightening
Decrease	Darkening

The data reflects changes in skin color where test site Baseline readings are considered 0% and the lightest (least dark - clear skin) skin color for each panelist is considered 100%. Clear skin is defined as a natural, untanned skin tone/color for each individual.



$$\%Improvement = \frac{y}{z-x} - \frac{x}{z-x}$$

7.0 Statistical Source Data:

The source data was Chromameter readings collected at Baseline and again after 14, 28 and 56 days of use. Chromameter data reflected changes in skin color where test site (Hyperpigmentation Area) baseline color intensity was considered 0% and the skin surrounding the test site Clear Skin – natural skin tone/color) was considered 100% improvement.

8.0 Results:

Please refer to attached Chart and Table.

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 Security Label Disclosure:

To prevent loss of and protect intellectual property, original, certified documents issued by AMA Laboratories Inc. can be identified by a proprietary, tamper evident security hologram affixed to all Conclusion/Signature pages on final reports. Any attempt to remove the hologram will irreversibly damage the label and leave an immediate trace, thus invalidating the document.

Only reports containing the AMA LABS, INC. hologram intact will be recognized by AMA Laboratories Inc. as a certified original.

12.0 Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, the test material (AMA Lab No.: M-8931, Client No.: CORUM, Whitening Spot Corrector (121127H)) demonstrated increases in L* value (Chromameter parameter) associated with skin lightening. The increases are considered statistically significant at each evaluation time point.

Hyperpigmentation Reduction - Skin Color Data			
	Day 14	Day 28	Day 56
% Difference:	*13.16%**	*23.34%**	*35.79%**
Max % Improvement:	*55.71%*	*66.67%*	*74.43%*

* Statistically Significant

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Date

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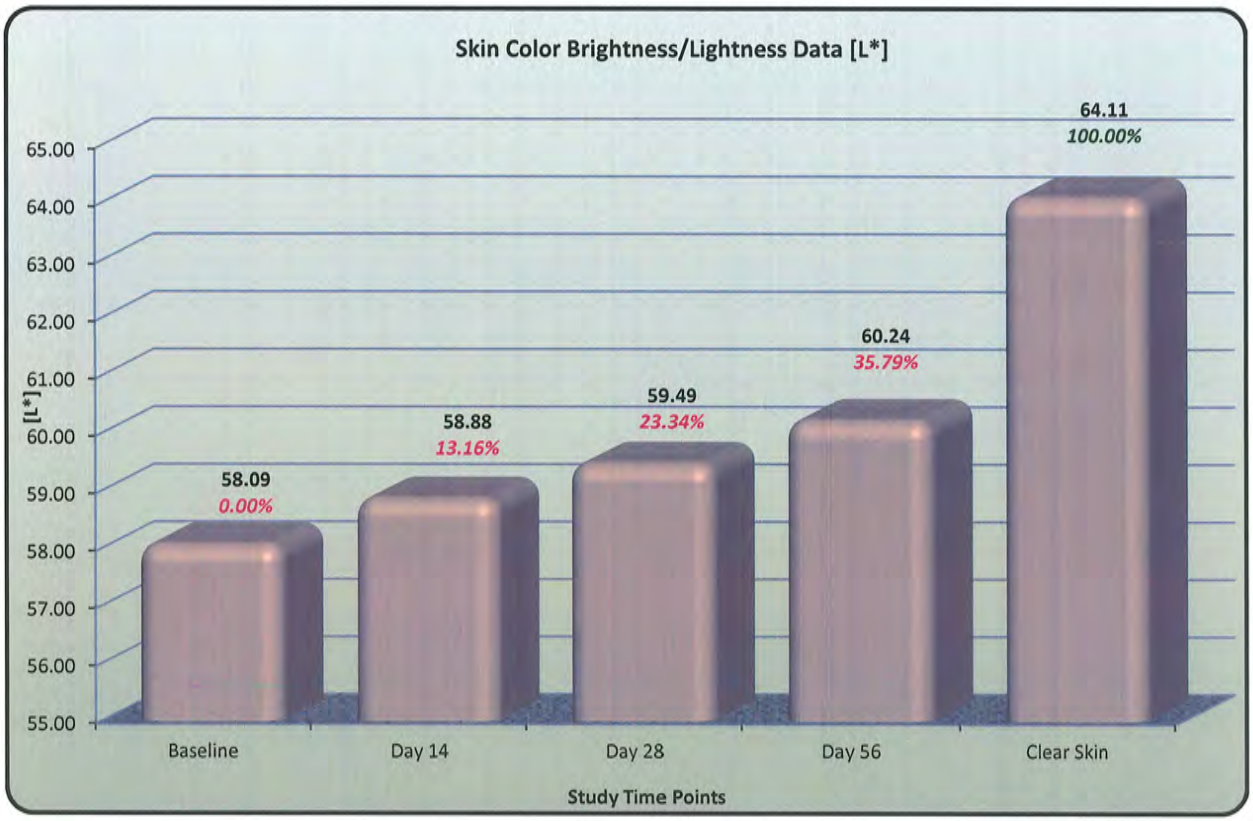
Skin Color Brightness/ Lightness Data [L*]								
AMA Lab No.:	M-8931							
Client No.:	CORUM, Whitening Spot Corrector (121127H)							
Panelist ID No.:	Baseline	Day 14	% Improvement - Individual Responses	Day 28	% Improvement - Individual Responses	Day 56	% Improvement - Individual Responses	Clear Skin
50 7429	56.63	56.77	*7.02%*	57.07	*22.81%*	57.53	*47.37%*	58.53
60 6514	58.97	59.00	*0.53%*	60.57	*25.40%*	61.13	*34.39%*	65.27
56 0324	53.57	54.67	*20.75%*	55.20	*30.82%*	56.43	*54.09%*	58.87
50 9511	62.07	62.60	*6.84%*	64.53	*31.62%*	65.80	*47.86%*	69.87
60 6151	54.37	54.90	*10.74%*	55.97	*32.21%*	56.13	*35.57%*	59.33
62 2570	64.23	65.10	*20.97%*	65.27	*25.00%*	66.20	*47.58%*	68.37
78 1836	59.30	59.73	*14.44%*	60.63	*44.44%*	60.70	*46.67%*	62.30
70 6457	59.07	59.43	*6.55%*	59.90	*14.88%*	59.60	*9.52%*	64.67
02 3680	60.23	60.60	*6.88%*	60.73	*9.38%*	61.97	*32.50%*	65.57
66 1927	58.00	58.83	*11.42%*	59.00	*13.70%*	59.43	*19.63%*	65.30
74 8871	55.03	59.10	*55.71%*	59.90	*66.67%*	60.47	*74.43%*	62.33
93 5892	54.73	57.27	*37.25%*	57.93	*47.06%*	58.00	*48.04%*	61.53
68 9137	61.00	61.80	*12.77%*	61.63	*10.11%*	62.23	*19.68%*	67.27
72 4447	57.40	57.83	*8.84%*	58.13	*14.97%*	59.73	*47.62%*	62.30
54 3619	60.67	60.90	*7.07%*	61.53	*26.26%*	62.13	*44.44%*	63.97
70 9516	57.07	58.10	*11.36%*	58.07	*10.99%*	62.23	*56.78%*	66.17
82 7129	53.70	53.97	*2.78%*	54.40	*7.29%*	54.63	*9.72%*	63.30
56 5122	52.07	52.47	*4.33%*	53.37	*14.08%*	53.43	*14.80%*	61.30
74 0062	63.37	63.10	*-4.26%*	63.77	*6.38%*	64.73	*21.81%*	69.63
21 8304	60.23	61.40	*19.02%*	62.23	*32.61%*	62.30	*33.70%*	66.37
Average:	**58.09**	**58.88**		**59.49**		**60.24**		**64.11**
% Improvement (L):*		*13.16%*		*23.34%*		*35.79%*		
p		0.002*		0.000*		0.000*		
t		3.678*		5.816*		7.230*		

* Statistically Significant



13.0 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:

Tasmiya Masud, B.A.
Quality Assurance Supervisor

7/24/14
Date