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AN INVESTIGATION INTO A TEST MATERIAL INTENDED TO REDUCE THE APPEARANCE OF FACIAL HYPERPIGMENTATION AND AGE SPOTS

AMA Ref. No.: MS13.INUSE.M8931.REP.CRM

Date: May 29, 2013

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. In addition, product effectiveness was evaluated photographically on 5 subjects via Reverse Photo Engineering.

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.

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		10
Number of subjects completing study		10
Age Range		25 - 48
Sex	Female	10
Race	Caucasian	9
	Asian	1

A subset of 5 subjects was selected for additional evaluation via Reverse Photo Engineering.

Number of subjects enrolled		5
Number of subjects completing study		5
Age Range		38-49
Sex	Female	5
Race	Caucasian	4
	Asian	1

6.0 Procedure:

Ten 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. Detailed, high resolution matched digital photographs were taken at baseline and again after 28 and 56 days 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 product treatment was photographically documented. This set of photographs thus provided a visual record of the efficacy of the product, on the subjects face.

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

MINOLTA CHROMAMETER COLOR COMPUTER READINGS

Instrumental Color Determinations to corroborate visual analysis were performed using a Minolta Chromameter or the equivalent (SmartProbe 400, IMS Inc). The Minolta CR-200 Chromameter interfaced with a DP-100 Color Computer System (Minolta CR-200) 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 human eye. Any increase in the a* coordinate is indicative of a reddening and increase in b* coordinate indicates yellow enhancement. Any increase in the L* coordinate indicates lightening of the color. Respectively, a decrease in the a* coordinate drives color toward the green shade, a decrease in the b* coordinate signifies a shift into the blue region and is perceived with a blue coefficient. Any diminution of the L* coordinate is indicative of the darkening of color.

Parameter:	L* Coordinate	a* Coordinate	b* Coordinate
Increase	Lightening	Reddening	Yellow
Decrease	Darkening	Green	Blue

REVERSE PHOTO ENGINEERING

Exclusively detailed, high resolution before and after digital photographs are taken, with fixed camera background, angles, settings, lighting, panelist positioning, color bars, white balance, standardized and digitally certified unretouched. Photographs are evaluated using image analysis software which allows the evaluation parameter to be captured and quantified.

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. Additional source data was set of detailed, high resolution digital image analysis software readings collected at Baseline and again after 28 and 56 days of use.

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 will be recognized by AMA Laboratories Inc. as a certified original.

13.0 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 reductions are considered statistically significant at each evaluation time point.

Hyperpigmentation Reduction - Skin Color Data			
	Day 14	Day 28	Day 56
% Difference:	*28.90%**	*41.07%**	*41.64%**
Max % Improvement:	62.84%	87.34%	87.97%

* Statistically Significant

Data was also obtained through matched scientific photography on a subset of five subjects. Image analysis software demonstrated that after 14, 28, and 56 days of usage, the test product reduced the appearance of age spots. Furthermore, the results are considered statistically significant at Day 14 and Day 56 timepoints.

Age Spot Reduction – Reverse Photo Engineering Data			
	Day 14	Day 28	Day 56
% Difference:	*-41.47%**	*-63.37%*	*-73.07%**
Max % Improvement:	-51.67%	-80.63%	-87.40%

* Statistically Significant

SIGNATURE PAGE

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6F, No. 360, Ruei Guang Road
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AMA Lab No.: M-8931

Client No.: CORUM, Whitening Spot Corrector (121127H)

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5/29/13

Date

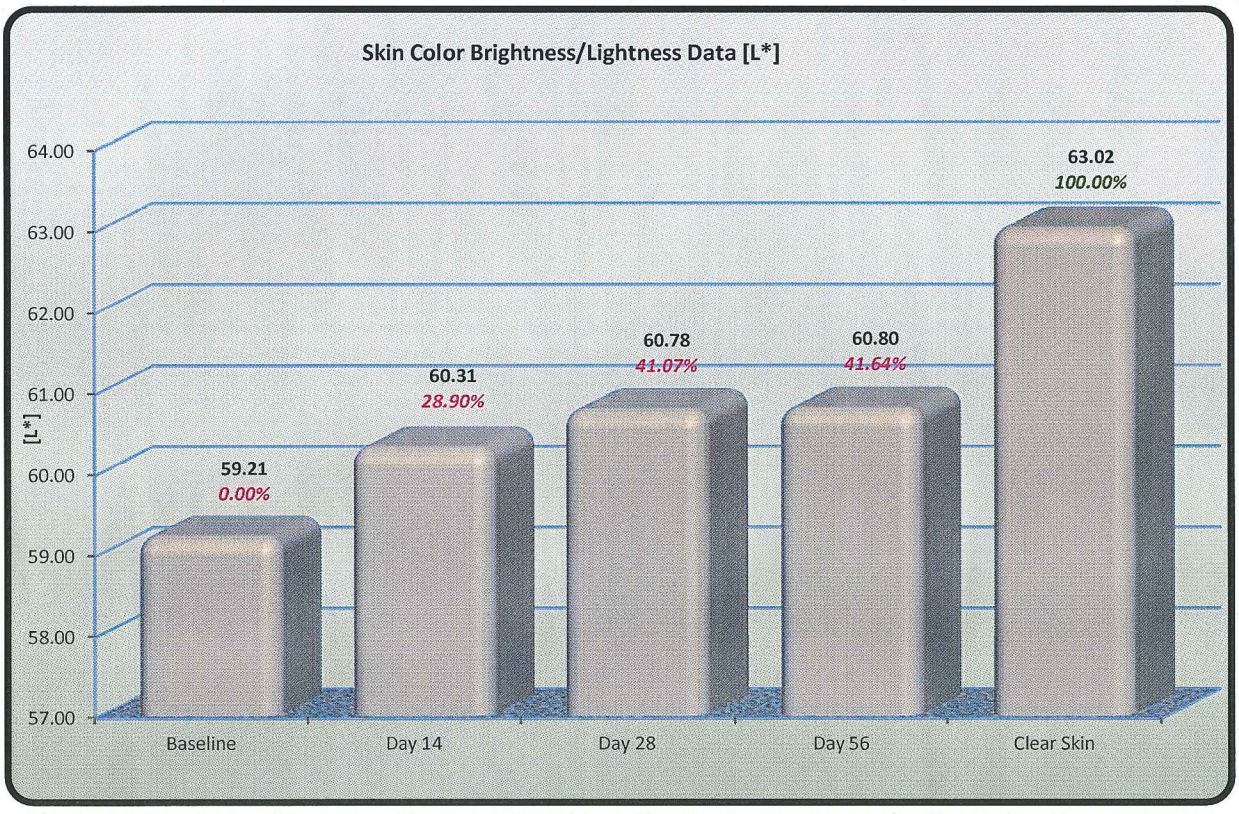
Note: All Services Undertaken Subject to the following General Policy: AMA Laboratories, Inc. Reports are submitted for exclusive use of the clients to whom they are addressed. Their significance is subject to the adequacy and representative character of the samples and to the comprehensiveness of the test, examination or surveys made. No quotations from AMA Laboratories, Inc., reports, or use of AMA Laboratories, Inc., name or names of staff members or sub-contractors is permitted except as expressly authorized in writing. The liability of AMA Laboratories, Inc. with respect to services rendered shall in no event exceed the amount of one hundred dollars. Any indemnification agreement attached to or included in the embodiment of this report shall, if sent by certified mail, return receipt requested, be deemed to be properly served, executed, notarized and accepted by virtue of the signature appearing on the return certified claim. Wherein this report is used to support commercial claims, the Sponsor is directed to provide said report in its entirety.

Skin Color Brightness/ Lightness Data - SUMMARY								
AMA Lab No.:	M-8931							
Client No.:	CORUM, Whitening Spot Corrector (121127H)							
Panelist ID No.:	Baseline	Day 14	% Improvement Individual Responses L*	Day 28	% Improvement Individual Responses L*	Day 56	% Improvement Individual Responses L*	Clear Skin
	L*	L*		L*		L*		L*
48 1671	62.43	63.90	*53.01%*	63.60	*42.17%*	63.67	*44.58%*	65.20
86 2755	59.43	59.67	*6.03%*	61.73	*59.48%*	61.53	*54.31%*	63.30
62 1925	60.90	61.53	*12.67%*	61.40	*10.00%*	61.57	*13.33%*	65.90
64 8203	59.03	62.13	*62.84%*	60.90	*37.84%*	61.53	*50.68%*	63.97
68 0518	54.73	57.27	*37.25%*	58.00	*48.04%*	57.93	*47.06%*	61.53
52 8237	58.47	58.73	*13.33%*	59.30	*41.67%*	59.17	*35.00%*	60.47
70 8706	57.53	57.53	*0.00%*	59.83	*87.34%*	59.85	*87.97%*	60.17
02 3080	58.03	58.37	*12.50%*	58.67	*23.75%*	59.17	*42.50%*	60.70
66 4980	59.10	60.47	*42.27%*	60.67	*48.45%*	59.90	*24.74%*	62.33
72 8719	62.47	63.53	*25.60%*	63.67	*28.80%*	63.67	*28.80%*	66.63
Average:	**59.21**	**60.31**	-	**60.78**	-	**60.80**		**63.02**
% Improvement (L*):		***28.90%***		***41.07%***		***41.64%***		
p		0.009*		0.000*		0.000*		
t		3.347*		5.648*		5.698*		

* Statistically Significant

	L* Coordinate
Increase	Lightening
Decrease	Darkening

Computer 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.

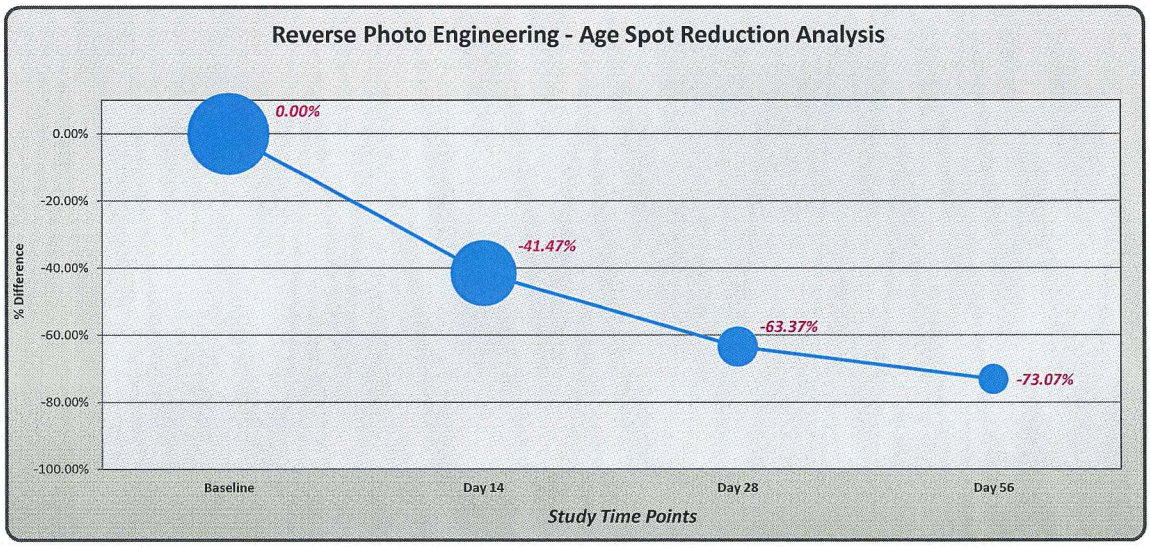


Reverse Photo Engineering - Age Spot Reduction Analysis							
AMA Lab Nos.:	Client Nos.:						
M-8931	CORUM, Whitening Spot Corrector (121127H)						
Panelist ID Nos.:	**Baseline [px]**	**Day 14 [px]**	***Individual % Difference:***	**Day 28 [px]**	***Individual % Difference:***	**Day 56 [px]**	***Individual % Difference:***
48 1671	20759	12975	-37.50%	5077	-75.54%	4208	*-79.73%*
52 8237	7682	5220	-32.05%	1488	-80.63%	968	*-87.40%*
60 1925	1975	972	-50.78%	765	-61.27%	416	*-78.94%*
68 0518	13235	8555	-35.36%	6172	-53.37%	2806	*-78.80%*
86 2755	7277	3517	-51.67%	3926	-46.05%	4330	*-40.50%*
Average % Difference:		***-41.47%***		***-63.37%***		***-73.07%***	
Max % Reduction:		***-51.67%***		***-80.63%***		***-87.40%***	
p		0.026*		0.054		0.048*	
t		3.443*		2.708		2.288*	

* - Statistically Significant

Student's t-test was used in this investigation. This is the test of the null hypothesis that the difference between two responses measured on the same statistical unit has a mean value of zero. In this investigation the changes in age spots (area affected by age spot measured in px^2) before and after the treatment were measured. If the treatment is effective, we expect the area affected by age spot for many of the patients to be smaller following the treatment. This is often referred to as the "paired" or "repeated measures" t-test. Dependent samples (or "paired") t-tests typically consist of a sample of matched pairs of similar units, or one group of units that has been tested twice (a "repeated measures" t-test). Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution. If the calculated p-value is below the threshold chosen for statistical significance (0.05 (5%)), then the null hypothesis (Null Hypotesis p>0.05) is rejected in favor of the alternative hypothesis.
Statistical analysis was computed using appropriate Excel statistical software functions, where one function returns the probability associated with a Student's t-Test and the other returns the t-value of the Student's t-distribution as a function of the probability and the degrees of freedom.

Reverse Photo Engineering
Exclusively detailed, high resolution before and after digital photography was 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 treatment regimen was photographically documented and the test area of involvement isolated. Photographs were evaluated using image analysis software which allows the age spots to be captured and quantified. The size of the area of involvement differed for each test panelist, therefore percent difference was calculated individually and then averaged.
[px^2] – Age Spot related pixels per area of involvement.



14.0 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

5/29/13
Date