

3892 Del Amo Boulevard •Torrance, California 90503 (310) 214-0043 • Fax(310) 370-3642 Web Site: www.bioscreen.com • E-Mail: info@bioscreen.com

### CLINICAL EVALUATION OF THE EFFICACY OF A SKIN CARE REGIMEN TO IMPROVE SKIN CONDITIONS

# ABBREVIATED SUMMARY REPORT

October 16, 2015

SPONSOR:	LifeWave 9444 Balboa Ave., Ste. 150 San Diego, CA 92123	
TEST PRODUCTS:	1) Daily Refresh Facial Nectar 2) Nightly Restore Facial Crème	

Nightly Restore Facial Crème
 Alavida Patch (Solution 29)

STUDY NUMBER: BCS 15-007

#### **RESEARCH STANDARD**

This clinical study was conducted in accordance with the International Conference of Harmonization Tripartite Guideline on Good Clinical Practice, applicable FDA regulations/guidelines set forth in 21 CFR Parts 11, and 50 and standard practices of BioScreen Testing Services.

## I. STUDY CONCLUSIONS

Under the conditions of the study the following claims were substantiated for Test Product Regimen: *Daily Refresh Facial Nectar, Nightly Restore Facial Crème, and Alavida Patch* (Solution 29):

- 1) Increased skin hydration
- 2) Improved skin firmness
- 3) Improved appearance of evenness of skin tone
- 4) Reduced appearance of fine lines and wrinkles (based on survey results)
- 5) Improvement in overall appearance of skin (based on survey results)

Test Product Regimen: *Daily Refresh Facial Nectar*, *Nightly Restore Facial Crème*, *and* <u>*Alavida Patch (Solution 29)*</u> provided statistically significant improvements after 10 minutes of test product(s) use resulting in an increase in skin hydration.

Test Product Regimen: *Daily Refresh Facial Nectar, Nightly Restore Facial Crème, and* <u>Alavida Patch (Solution 29)</u> provided statistically significant improvements after 24 hours of test product(s) use resulting in an increase in skin hydration.

Test Product Regimen: *Daily Refresh Facial Nectar, Nightly Restore Facial Crème, and Alavida Patch (Solution 29)* provided statistically significant improvements after 1 week of test product(s) use resulting in an increase in consumer perception of overall improvement in skin complexion and appearance of their skin, including "healthy glow" and "radiance."

Test Product Regimen: *Daily Refresh Facial Nectar, Nightly Restore Facial Crème, and* <u>Alavida Patch (Solution 29)</u> provided statistically significant improvements after 3 weeks of test product(s) use resulting in an increase in skin hydration, skin firmness, appearance of evenness of skin tone, and consumer perception of overall improvement in skin complexion and appearance, including "healthy glow" and "radiance."

Test Product Regimen: *Daily Refresh Facial Nectar, Nightly Restore Facial Crème, and* <u>Alavida Patch (Solution 29)</u> provided statistically significant improvements after 6 weeks of test product(s) use resulting in an increase in skin hydration, skin firmness, and appearance of evenness of skin tone, and consumer perception of overall improvement in skin complexion and appearance, including "healthy glow" and "radiance."

## **II. SUMMARY OF RESULTS**

Under conditions of the study a total of 51 healthy male and female subjects, 41-65 years of age, completed the clinical study evaluating the efficacy of <u>Test Product Regimen</u>: *Daily Refresh Facial Nectar, Nightly Restore Facial Crème, and Alavida Patch (Solution 29)*.

### A. Skin Hydration by Corneometer

### **Clinical Findings:**

- There was a statistically significant improvement in skin hydration from baseline at 10 minutes, 24 hours, 3 weeks, and 6 weeks post-treatment.
- A statistically significant number of subjects demonstrated an improvement in skin hydration from baseline 10 minutes, 24 hours, 3 weeks, and 6 weeks post-treatment.

### B. Skin Firmness by Cutometer

### **Clinical Findings:**

- There was a statistically significant improvement in skin firmness from baseline at 3 weeks and 6 weeks post-treatment.
- A statistically significant number of subjects demonstrated an improvement in skin firmness from baseline 3 weeks and 6 weeks post-treatment.

### C. Evenness of Skin Tone by Visual Grading

### **Clinical Findings:**

• There was a statistically significant improvement in the appearance of evenness of skin tone from baseline at 3 weeks and 6 weeks post-treatment.

#### D. Post-Treatment Questionnaire

#### Survey Results:

SCALE: Questions #1-3, #7, #9-17, #20-28, and #31-33: *1= No, Strongly Disagree, 2= No, Disagree, 3= Yes, Agree, 4= Yes, Strongly Agree*Questions #4-6, #8, #18-19, and #29-30: *1= No, Strongly Disagree, 2= No, Disagree, 3= Yes, Agree, 4= Yes, Strongly Agree*, 5= N/A
Question #34: 1= Fine Lines and Wrinkles, 2= Texture of My Skin, 3= Skin Hydration and Moisturization, 4= Appearance of Even Skin Tone
Questions #35-37: 1= Yes, 2= No
Questions #39-40: 1= Very Good, 2= Good, 3= Poor, 4= Very Poor

Post-Treatment Statement	% of subjects with favorable response		
1 ost-11 catment Statement	Week 1	Week 3	Week 6
1. My skin had a reduction in the appearance of fine lines and wrinkles.	76.47%	78.43%	86.27%
2. My skin had a reduction in the appearance of fine lines and wrinkles in my forehead.	74.51%	76.47%	86.27%
3. My skin had a reduction in the appearance of "crow's feet", lines and wrinkles around the eye.	66.67%	82.35%	78.43%
4. My skin had a reduction in the appearance of	59.18%	60.00	70.00%
<ul><li>deep wrinkles.</li><li>5. My skin had a reduction in the appearance of smile lines.</li></ul>	(n=49) 59.18% (n=49)	(n=50) 77.55% (n=49)	(n=50) 77.55% (n=49)
6. My skin had a reduction in the appearance of vertical wrinkles between my brows.	56.00% (n=50)	58.00% (n=50)	<b>71.43%</b> (n=49)
7. The overall quality of my skin complexion has improved.	78.43%	88.24%	84.31%
8. The appearance of sun damage spots is visibly reduced.	65.31% (n=49)	<b>71.11%</b> (n=45)	<b>71.74%</b> (n=46)
9. The firmness of my skin has improved.	78.43%	84.31%	80.39%
10. The elasticity of my skin has improved.	80.39%	76.47%	80.39%
11. The texture of my skin has improved.	84.31%	90.20%	88.24%
12. The smoothness of my skin has improved.	90.20%	90.20%	90.20%
13. The softness of my skin has improved.	88.24%	88.24%	96.08%
14. My skin looks more luminous / radiant, or has a "healthy glow".	72.55%	74.51%	76.47%

15. My skin looks brighter.	76.47%	78.43%	68.63%
16. My skin tone appears more even.	74.51%	80.39%	74.51%
17. My skin has a decrease in discoloration.	54.90%	62.75%	64.71%
18. My skin appears less blotchy.	67.39% (n=46)	<b>72.92%</b> (n=48)	<b>72.92%</b> (n=48)
19. My skin tone has less of a red or ruddy appearance.	63.64% (n=44)	<b>70.21%</b> (n=47)	<b>76.60%</b> (n=47)
20. I've noticed an overall improvement in the appearance of my skin.	82.35%	86.27%	84.31%
21. My skin feels more hydrated and moisturized.	88.24%	92.16%	94.12%
22. My skin feels more hydrated and moisturized instantly after application of the product.	84.31%	96.08%	96.08%
23a. Do you feel you look younger?	49.02%	68.63%	72.55%
23b. If yes, how many years younger? 1= 0-1 Years, 2= 2-4 Years, 3= 5-9 Years, 4= 10-14 Years, 5= 15 Years or More	1=44.00% 2=44.00% 3=12.00% 4=4.00% 5=0.00% (n=25)	1=44.00% 2=80.00% 3=16.00% 4=0.00% 5=0.00% (n=34)	1=44.00% 2=84.00% 3=16.00% 4=4.00% 5=0.00% (n=37)
24. I am pleased with my results at X weeks	88.24%	86.27%	90.20%
25. I am amazed by my results at X weeks	58.82%	66.67%	72.55%
26. My results keep getting better after each week of use.	78.43%	66.67%	78.43%
27. I like the smell of the product	82.35%	80.39%	82.35%
28. The product absorbs into my skin well	98.04%	96.08%	96.08%
29. I am able to put my makeup on afterwards without any issue	<b>93.33%</b> (n=30)	<b>92.86%</b> (n=28)	<b>96.30%</b> (n=27)
30. I feel that this product could serve as both my moisturizer and anti-aging product treatment (dual action).	<b>84.00%</b> (n=50)	<b>81.63%</b> (n=49)	77.55% (n=49)
31. The patch didn't cause any irritation.	96.08%	96.08%	96.08%
32. The patch was easy to apply and comfortable.	94.12%	92.16%	94.12%
33. The patch stayed on the entire time I was wearing it.	96.08%	96.08%	88.24%

34. Which results would you consider offered dramatic improvement during your use of the product? (please circle all that apply)	1= 54.90% 2= 56.86% 3= <b>84.31%</b> 4= 50.98%	1= 50.98% 2= 49.02% 3= <b>70.59%</b> 4= 52.94%	1=50.98% 2=50.98% 3=60.78% 4=50.98%	
35. Would you consider this one of the best product regimens that you have ever used?	72.55%	70.59%	72.55%	
36. Now that you have used the test products, would you buy them if they were available at stores where you normally shop?	76.47%	76.47%	80.39%	
37. I would recommend these test products to a friend or family member.	82.35%	82.35%	82.35%	
38. What, if anything, did you <u>like</u> about the test products?	See Below	See Below	See Below	
39. Please rate the <b>Night Formula</b> on the following list of characteristics:				
39a. Ease of application:	100.00%	100.00%	100.00%	
39b. Leaving skin feeling comfortable:	100.00%	100.00%	100.00%	
39c. Soothing to skin:	96.08%	100.00%	100.00%	
40. Please rate the <b>Day Formula</b> on the following list of characteristics:				
40a. Ease of application:	100.00%	100.00%	98.04%	
40b. Leaving skin feeling comfortable:	100.00%	100.00%	100.00%	
40c. Soothing to skin:	96.08%	100.00%	100.00%	

0) Joantia ado

Jordan DeSantis Clinical Supervisor

popula.

Anthea Dransfield Director, Quality Assurance