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**CLINICAL EVALUATION OF THE EFFICACY OF A SKIN CARE PRODUCT
TO IMPROVE SKIN CONDITIONS**

FINAL REPORT

May 12, 2014

SPONSOR: LifeCell South Beach Skincare
1909 Tyler Street, Suite 701
Hollywood, FL 33020

TEST PRODUCT: South Beach Skincare #ORGA Lifecell Cream, Form#
30035-02

STUDY NUMBER: BCS 14-301

PROJECT NUMBER: 839560

Microbiology • Analytical Chemistry • Clinical Safety & Claims

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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 and based on the study results, the following claims were substantiated for the Test Product: South Beach Skincare #ORGA Lifecell Cream, Form# 30035-02:

- 1) Increase in skin hydration
- 2) Increase in skin firmness
- 3) Reduction in the appearance of fine lines and wrinkles in the eye area.

II. SUMMARY OF RESULTS

Under conditions of the study a total of 32 healthy female subjects, 35-64 years of age, completed the clinical study evaluating the efficacy of Test Product: South Beach Skincare #ORGA Lifecell Cream, Form# 30035-02 to improve facial skin conditions.

A. Skin Hydration by Corneometer

Note: Positive difference indicates improved skin hydration.

Parameter	Week 8
Mean Percent Difference From Baseline	12.61%
Percent of Subjects with Increased Skin Hydration	84.38%

BOLD values indicate statistical significance ($p \leq 0.05$)

Clinical Findings:

- There was a statistically significant improvement in skin hydration from baseline at 8 weeks post-treatment.
- A statistically significant number of subjects demonstrated improvement in skin hydration at 8 weeks post-treatment.

B. Skin Firmness by Cutometer

Note: Negative difference indicates improvement in the appearance of skin firmness.

Parameter	Week 8
Mean Percent Difference From Baseline	-9.27%
Percent of Subjects with Improved Skin Firmness	87.50%

BOLD values indicate statistical significance ($p \leq 0.05$)

Clinical Findings:

- There was a statistically significant improvement in skin firmness from baseline at 8 weeks post-treatment.
- A statistically significant number of subjects demonstrated improvement in skin firmness at 8 weeks post-treatment.

C. Fine Lines and Wrinkles of the Eye Area by Visual Grading

SCALE: 0 = None, 1-3 = Mild, 4-6 = Moderate, 7-9 = Severe

Note: Negative difference indicates improvement in the appearance of fine lines and wrinkles of the eye area.

Parameter	Week 8
Mean Percent Difference From Baseline	-2.16%
Percent of Subjects with Improved Appearance of Fine Lines and Wrinkles of the Eye Area	28.13%

BOLD values indicate statistical significance ($p \leq 0.05$)

Clinical Findings:

- There was a statistically significant improvement in appearance of fine lines and wrinkles in the eye area from baseline at 8 weeks post-treatment.

D. Post-Treatment Questionnaire (Week 8)

SCALE: 1=Yes, 2=No

Question	% of subjects with favorable responses
	Week 8
1. Did you notice any difference in the appearance of your skin after using Lifecell?	78.13%
2. Did the appearance of wrinkles diminish with LifeCell?	65.63%
3. Does your skin look and feel smoother?	87.50%
4. Does your skin look and feel firmer?	68.75%
5. Did you see an improvement in the overall look of your skin?	75.00%
6. Did you notice an improvement in the appearance of your skin 1 minute after application?	43.75%
7. How long did it take to notice any difference in your skin while using LifeCell?	See Below

BOLD values indicate statistical significance ($p \leq 0.05$)

							improvement.
17655	1	1	1	2	1	2	1 1/2 months I started noticing wrinkles diminishing and skin smoother
17659	1	2	1	2	2	2	no difference in skin was noticed (verbal confirmation)
17663	2	2	2	1	2	2	no difference in skin was noticed (verbal confirmation)
17742	1	1	1	1	1	1	7 Wks.
17792	1	1	1	1	1	1	It took a few weeks to really see anything visible. But I felt it almost immediately. It's subtle but the product did do its job
17894	1	1	1	1	1	2	The first week
17895	1	1	1	1	1	2	Not sure but after about a week I got compliments on my skin.

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