

## **ST&T Research Departments:**

*PRODUCT DEVELOPMENT & CLINICAL RESEARCH*

*DRUG-DEVICES-COSMETICS-SUPPLEMENTS-FOOD/BEVERAGE*

*US AGENT FDA-FTC-EPA-CUSTOMS - & GRAS REGISTRATION*

*LABELING & INTERNATIONAL REGULATORY CONSULTATION*

*PRE & POST- MARKET CONSUMER PRODUCT USE RESEARCH*

*INFORMATION & CONSULTING: 800-869-4636*



**July 14, 2011**

## **FINAL REPORT**

### **STUDY NSC-AW-4: RESULTS OF A CLINICAL STUDY INTENDED TO EVALUATE THE EFFECTS OF A TOPICAL EVENING AGE-DEFYING/ANTI-WRINKLE COSMETIC CREAM**

**Background:** Anti-aging skin creams are abundant in today's cosmetic marketplace. Newer ingredients that may provide additional efficacy are sought to improve existing products. This study investigates the safety and efficacy of two such ingredients, a soluble Nerium oleander extract (NAE-8™) and proprietary protein blend (collagen, elastin, glycosaminoglycans)

**Study Methods:** Thirty-five (35) subjects were enrolled in a single-site, open-label Pilot Study to evaluate the safety and efficacy of NAE-8™ in reducing the appearance of aged skin related wrinkles and sun damage. The composition described in this study is a topical skin cream, which was formulated with a Nerium oleander extract suspended in a base cream "carrier" to facilitate application.

Subjects were instructed to apply the study product to the face for four (4) consecutive weeks. Subject evaluations were conducted at the initial visit and after 7, 14, and 28 days of application.

Primary outcomes included (1) an objective evaluation of changes in the appearance of wrinkles and other aging and sun damaged-looking skin of the face, using an advanced fluorescence spectroscopy skin analyzer, and (2) the subjects' perception of changes in the appearance of their aged and sun-damaged face in terms of wrinkling, discoloration, complexion, tone and smoothness, as reported by questionnaire administered at the end of weeks 2 and 4.

Secondary outcomes included (1) an objective assessment of safety to determine if dermal application of the active ingredient was absorbed systemically, and (2) subjective input from subjects regarding skin irritation.

**Results:** The study population varied in age, amount of wrinkles, and Fitzpatrick score. A total of thirty-five (35) subjects were enrolled, and thirty-four (34) subjects completed the entire study.

Daily application of the NAE-8™ has demonstrated:

**Week Two:**

- Overall 30% reduction in the appearance of deep wrinkles, 22% reduction in the appearance of emerging, 20% fine lines, and 25% reduction in the appearance of discoloration spots within 2 weeks.

**Week Four:**

- Effectiveness of treatment persisted throughout duration of the study, with overall 33% reduction in the appearance of deep wrinkles, 24% reduction in the appearance of emerging, 18% fine lines, and a 20% reduction in the appearance of discoloration spots after 4 weeks.

Subject comments corroborated these clinical observations in detail. (See Example of Study Participant #519 Below)

The subjects rated overall product effectiveness with a score of 7 on a scale of 1 to 10, with 10 being most effective.

The only negative or adverse observations from study subjects or clinical staff were two cases of mild skin dryness.

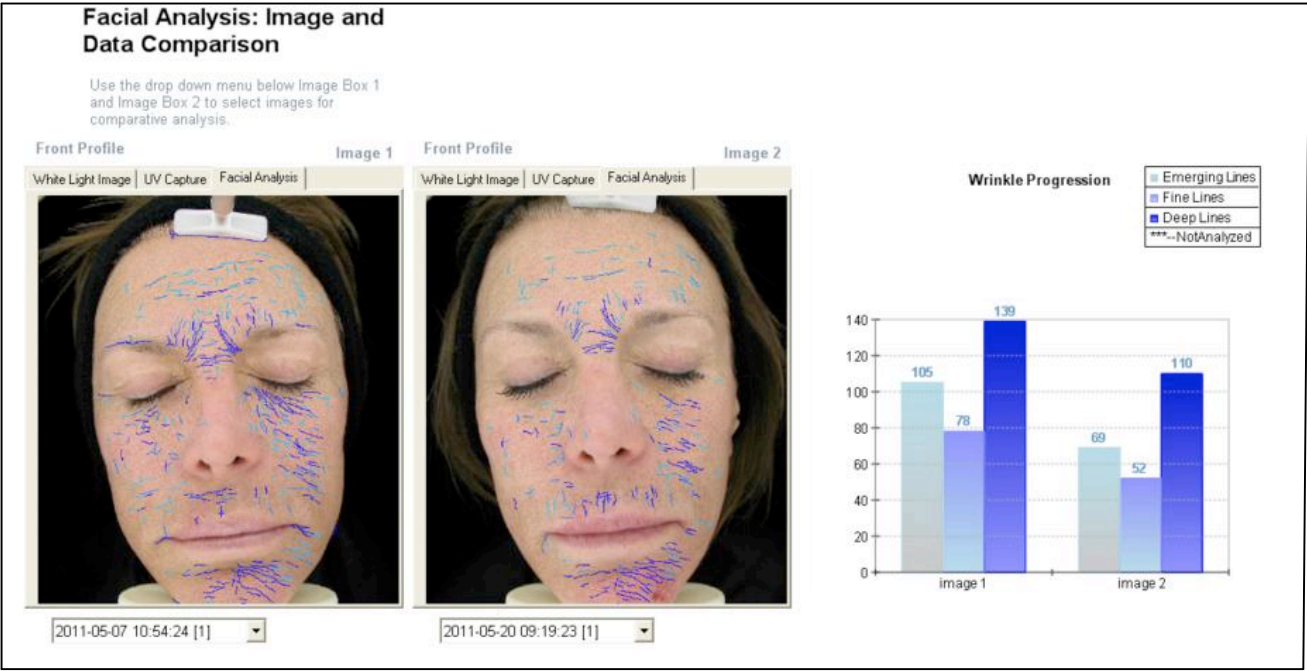
The active ingredient, Nerium oleander extract (NAE-8™), was not absorbed systemically into the blood in any of the study subjects as verified by laboratory analysis of samples taken from each participant.

**Table of the quantitative skin analysis data is presented in detail here:**

		<i>Baseline</i>	<i>Appearance Change 2 Weeks</i>	<i>Appearance Change 4 Weeks</i>
<b>Face Cream 4 weeks use</b>	<b>Emerging (E)</b>	<b>100%</b>	<b>22%</b>	<b>24%</b>
	<b>Fine (F)</b>	<b>100%</b>	<b>20%</b>	<b>18%</b>
	<b>Deep (D)</b>	<b>100%</b>	<b>30%</b>	<b>33%</b>
	<b>Discoloration</b>	<b>100%</b>	<b>25%</b>	<b>20%</b>
	<b>(E+F+D)</b>	<b>100%</b>	<b>22%</b>	<b>24%</b>
	<b>n=</b>	<b>34</b>	<b>34</b>	<b>34</b>

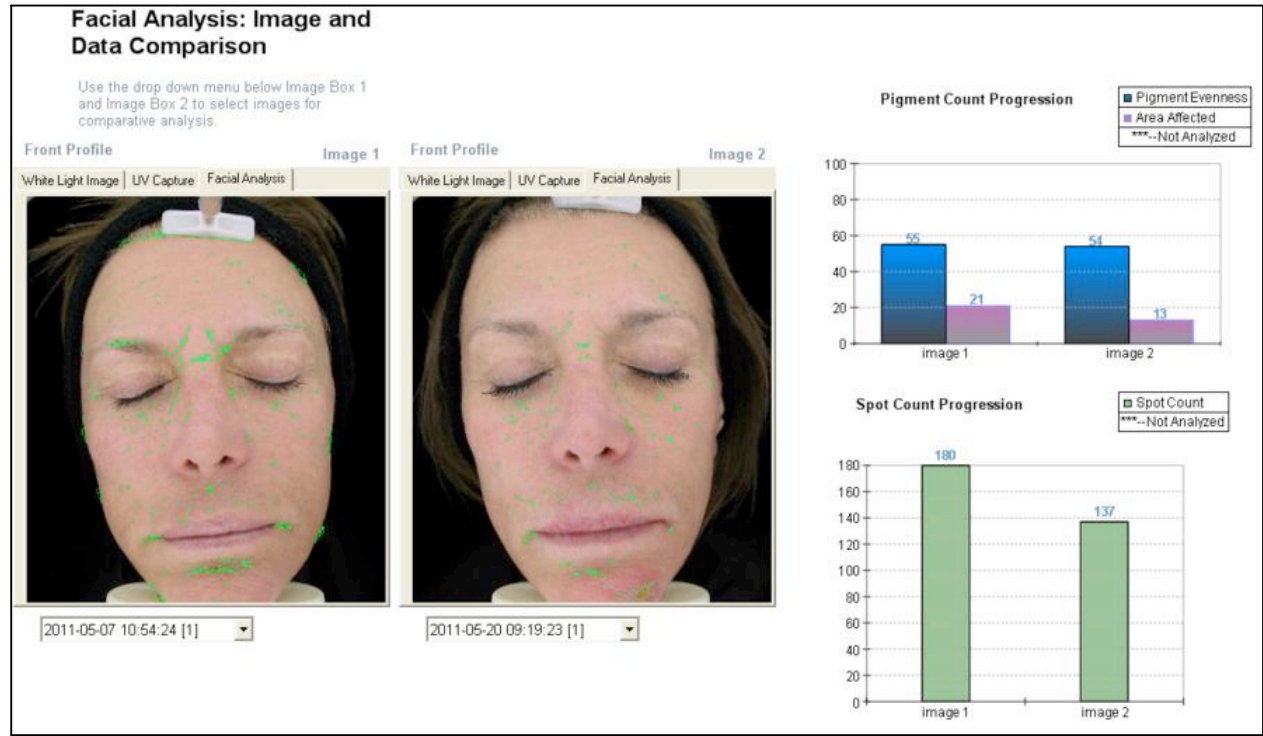
## Clinical Photographs and Corresponding Quantitative Skin Analysis

### Subject: BRPO-519 -- Wrinkle and Discoloration Spots Count Changes in 14 Days



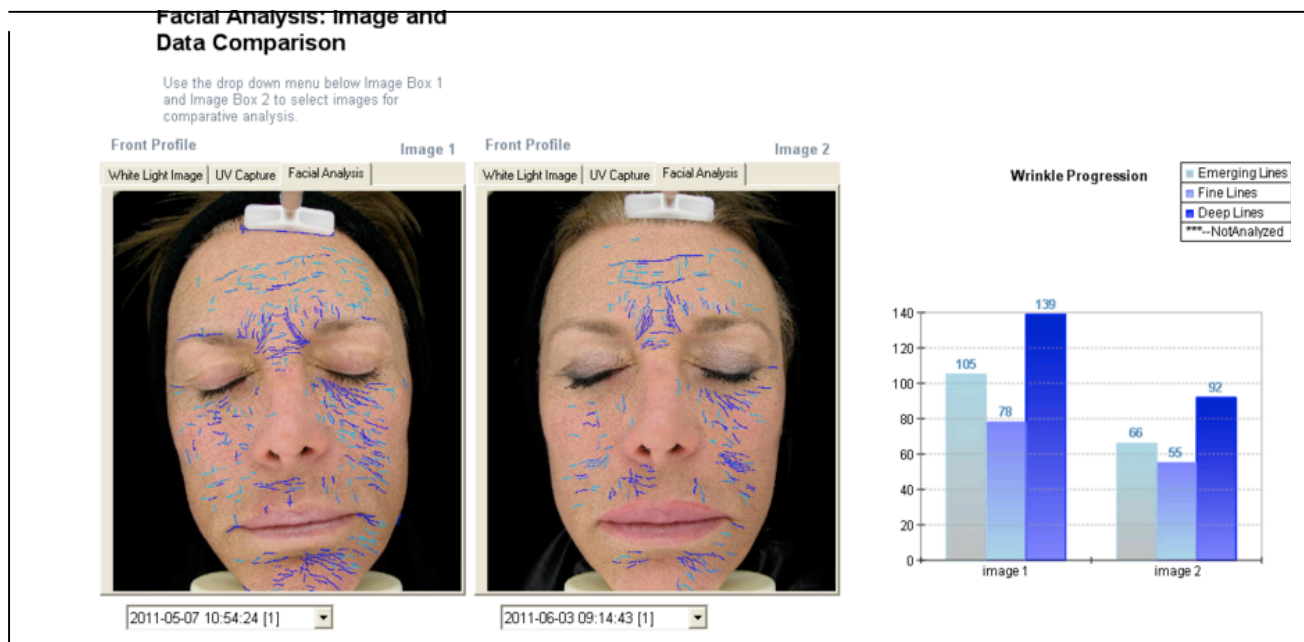
#### Effect of 14 days daily application of Nerium AD Night Cream on wrinkles

Emerging Lines	Fine Lines	Deep Lines
34% (-)	33% (-)	21% (-)

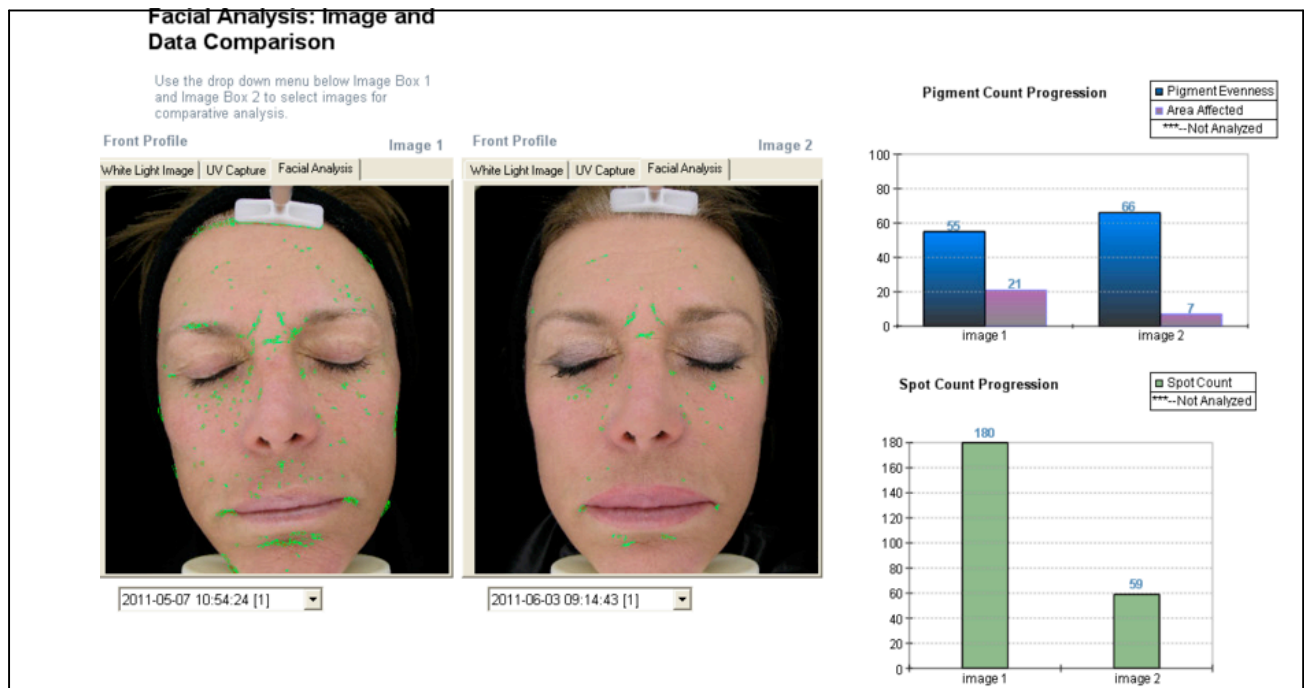


#### Effect of 14 days daily application of Nerium AD Night Cream on discoloration spots

Discoloration Evenness	Area Affected	Spot Count
2% (-)	38% (-)	24% (-)

**Subject: BRPO-519 -- Wrinkle and Discoloration Spots Count Changes in 28 Days****Effect of 28 days daily application of Nerium AD Night Cream on wrinkles**

Emerging Lines	Fine Lines	Deep Lines
37% (-)	30% (-)	34% (-)

**Effect of 28 days daily application of Nerium AD Night Cream on discoloration spots**

Discoloration Evenness	Area Affected	Spot Count
20% (+)	67% (-)	72% (-)

**Investigators:**

Larry K. Fan, MD, and study personnel at: Science, Toxicology & Technology – Product Research

**Clinic Sponsor:**

Nerium SkinCare Inc.

**Data Collection Period:**

Study Completion June 2011

**Study Aim/Purpose:**

Was to determine the safety and efficacy of the NeriumAD Night Cream for the appearance of wrinkle reduction, smoothing, clearing, softening, and toning of aged and sun damaged skin.

**Prepared by:**

**Ronald J. Amen, Ph.D.**

**ST&T - Director of Clinical Research**

A handwritten signature in black ink, appearing to read "Ronald J. Amen". The signature is written in a cursive, flowing style.