

**AN EIGHT (8) WEEK, HALF-FACE, SINGLE-BLIND,  
CONTROLLED EVALUATION OF THE EFFECTS  
OF SKIN TREATMENT PRODUCTS ON SKIN CONDITION**

**FINAL REPORT**

**STUDY NO. 2060GL0104  
VERSION 1.2**

**Submitted to:  
GeneLink, Inc.  
June 10, 2004**

**INVESTIGATOR:**

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**SITE:**

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**STUDY COORDINATOR:**

Diane Orino, M.A.,C.C.R.C.



June, 2004

GeneLink, Inc.  
100 South Thurlow  
Margate, NJ 08402  
P.O. Box 3212  
Margate, NJ 08402

Re: An Eight (8) Week, Half-Face, Single-Blind, Controlled Evaluation Of The Effects Of  
Skin Treatment Products On Skin Condition; IRSI 2060GL0104

This report accurately reflects the data derived from the procedures and materials tested in this study. The conclusions are based on an interpretation of the data and have been reviewed by the Principal Investigator and by personnel from International Research Services, Inc. responsible for assuring its accuracy.

*EK Boisits 6/10/04*

Edward K. Boisits, Ph.D.  
Vice President, Clinical Research

*Robert A. Murray 6/10/04*

Robert A. Murray, C.C.R.P.  
Vice President, Operations and QA

*Stephen R. Schwartz 06.10.04*

Stephen R. Schwartz  
President

## 1.0 SUMMARY

The objective of this study was to evaluate if skin care products custom made for various individuals using their *Dermagenics*<sup>™</sup> profiles showed improved performance over individuals using placebo creams in which the custom ingredients were left out. Forty-four (44) subjects consented to participate in the study on 1/14/04. Each subject then underwent a *Swabbing Genetic Profile Measurement*. The study was initiated on February 19, 2004 and completed on April 14, 2004. Thirty-one (31) subjects were enrolled and twenty-nine (29) completed the study. Two (2) subjects were discontinued due to inability to complete the final visit.

In conclusion, under the conditions employed in this study, results of clinical assessment of product performance suggests overall improvement in skin condition as a function of time through the use of the **Active** product. Results of the survey/questionnaire administered at days 14, 28 and 56 suggest the **Active** product as the overwhelmingly favored treatment, as shown by the greater number of affirmative responses. The **Active** product numerically out-performed the placebo treatment group, with strong statistically significant events in superficial fine lines/wrinkles, suppleness and firmness/elasticity/resiliency. These findings were corroborated by the results of the *forced choice analysis*, wherein the data indicated that the **Active** product significantly out-performed the placebo. These findings suggest that with a larger sample size, numerical differences may become even more significant, thereby further showing a comparative advantage for the **Active** product relative to the placebo group.

## **1.0 SUMMARY (Continued)**

These findings suggests that with a larger sample size, numerical differences may become significant, thereby showing a comparative advantage for the **Active** product relative to the placebo group. Results of the survey/questionnaire administered at days 14, 28 and 56 suggest the **Active** as the overwhelming favored treatment, as shown by the greater number of affirmative responses.

## **2.0 OBJECTIVE**

The objective of this study was to evaluate if skin care products custom made for various individuals using their *Dermagenics*<sup>™</sup> profiles showed improved performance over individuals using placebo creams in which the custom ingredients were left out. The following parameters were assessed:

1. Improvement in the uniformity pigmentation.
2. Improvement in skin dryness.
3. Reduction in the clinical appearance of superficial fine lines/wrinkles.
4. Improvement (increase) in skin elasticity/firmness/resiliency.
5. Improvement in skin suppleness.
6. Improvement in skin tone

## **3.0 BACKGROUND**

GeneLink, Inc. has developed a cosmetic skin treatment product that they feel will improve skin condition. The product is prepared based on individual's genetic predisposition to certain oxidative and erythematous stresses. It was their desire to enter into a clinical study that would develop data to establish efficacy.

## **4.0 CLINICAL SITE**

International Research Services, Inc.  
385 Main Street  
Rockland, ME 04841

## **5.0 STUDY PERSONNEL**

### **5.1 INVESTIGATOR:**

Edward K. Boisits, Ph.D.

### **5.2 DERMATOLOGIST:**

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Board Certified in Dermatology  
Designate: Ali Auclair, P.A.-C

### **5.3 STUDY COORDINATOR:**

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