



**Stephens**

A Global Research Company

**AN 10-WEEK PILOT CONSUMER PERCEPTION TEST TO EVALUATE THE  
OVERALL ACCEPTABILITY OF A VIVISCAL ORAL SUPPLEMENT WHEN  
USED BY FEMALES WITH SELF-PERCEIVED THINNING HAIR**

**Prepared for:**

**Life's 2 Good**

**James Murphy**

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**Thomas J. Stephens & Associates, Inc.**

**Stephens Study Number: C09-D309**

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**PURPOSE**

This pilot consumer research study was conducted for Life's 2 Good to evaluate the overall acceptability of a Viviscal supplement in female subjects with self-perceived thinning hair associated with poor diet, stress, hormonal influences, or abnormal menstrual cycles.

Viviscal (Regular or Maximum Strength) is an oral food supplement specifically designed to promote existing hair growth for women suffering from temporary thinning hair. The key ingredient is AminoMar C – a rich protein compound of marine extracts blended with organic, soluble silica and fortified with Vitamin C. Viviscal provides essential nutrients to nourish hair naturally from within. Viviscal works in four stages over several months of use to improve the appearance of thinning hair:

STAGE 1: Nourishes the hair follicles

STAGE 2: Strengthens and promotes the growth of existing hair

STAGE 3: Supports the growth of existing hair where it has slowed down or temporarily stopped

STAGE 4: Hair becomes stronger, healthier, and more vibrant

**GENERAL INFORMATION**

Stephens and Associates Study Number: C09-D309

Test: An 10-Week Pilot Consumer Perception Test to Evaluate the Overall Acceptability of a Viviscal Oral Supplement When Used by Females with Self-Perceived Thinning Hair

Test Material: Viviscal Oral Supplement (60 tablets per box)

Investigator: Thomas J. Stephens, Ph.D.

Sub-Investigator/Study Physician: James H. Herndon, Jr., M.D., FAAD,  
Board Certified Dermatologist

Clinic Manager: Barbara Hammond, B.S.

Biostatistics Manager: Paul Kavanaugh, M.S.

Quality Assurance Manager: Monae Miller, MHA, CCRC

Testing and Administrative Facility: Thomas J. Stephens & Associates, Inc.  
Dallas Research Center  
3310 Keller Springs Road, Suite 130  
Carrollton, Texas 75006

Sponsor: Life's 2 Good  
7 Racecourse Business Park Ballybrit  
Galway, Ireland

Sponsor's Representative: James Murphy

Experiment Start Date: January 05, 2010

Experiment End Date: March 16, 2010

## **SUMMARY**

This pilot consumer research study was conducted for Life's 2 Good to evaluate the overall acceptability of a Viviscal supplement in female subjects with self-perceived thinning hair associated with poor diet, stress, hormonal influences, or abnormal menstrual cycles. Sixteen (16) female subjects with self-perceived thinning hair associated with poor diet, stress, hormonal influences, or abnormal menstrual cycles completed the study.

During the course of the study, subjects consumed two tablets of the test material per day (one in the morning and one in the evening) with water, after eating. Clinical evaluations were conducted at Baseline (Visit 1), Week 4 (Visit 2), and Week 10 (Visit 3).

At each visit, subjects had their hair washed by clinic staff with shampoo over a sink containing cheesecloth. The cheesecloth was positioned to collect shedding hair. The number of hairs collected in the cheesecloth were counted and recorded.

At Week 4 and Week 10, subjects completed Self-Assessment Questionnaires regarding the health of their hair.

Results show that Life's 2 Good's Viviscal supplement was well received by test subjects. Analyses of hair counts showed a directional reduction in hair shedding over the 10 week period. A greater proportion of subjects responded favorably than unfavorably to questionnaires about improved hair volume, better scalp coverage, improved thickness of hair body, improved softness, improved hair shine, reduced hair shedding, improved nail strength and growth rate and overall skin health.

## **STORAGE, HANDLING, AND DOCUMENTATION OF TEST MATERIALS**

The receipt of test materials by Stephens & Associates was documented in a log book, which serves as a permanent record of the receipt, storage, return, and disposition of all study materials. All study materials were kept in a locked product-storage room accessible to clinical staff members only. At the conclusion of the clinical study, the study test materials were destroyed in accordance with all applicable regulations.

## **TEST MATERIAL DESCRIPTIONS**

Test Material Identification Number (TMIN): 1114-09C  
Sponsor Test Material Identification: Viviscal Oral Supplement (60 tablets per box)  
Physical Description: Light-brown, opaque solid

## **INFORMED CONSENT**

Written informed consent conforming to 21 Code of Federal Regulations 50.25 was obtained from each subject prior to enrollment in the study. The original, signed Informed Consent Agreement for each subject participating in the study will be retained in the study file. Each subject received a signed copy of the agreement. (Please see Appendix IV for a copy of the Informed Consent Agreement.)

## **ATTRITION**

Sixteen (16) subjects completed study participation. Nineteen (19) subjects enrolled to participate in the study, and three (3) subjects discontinued study participation due to the following reasons:

- Voluntarily withdrew: Subject 009
- Adverse event: Subject 012
- Non-compliance with usage instructions: Subject 018

(Please see Appendix V for a copy of the Attrition Form listing the dates of and reasons for the attrition.)

## **ADVERSE EVENT**

One subject experienced an adverse event during the course of the study. A brief description of the adverse event (including the relationship to the test material and the dates of the adverse event onset and resolution) is presented below. (Please see Appendix VI for a complete copy of the Adverse Event Form.)

Subject Number: 012  
Description of Adverse Event: Subject reported experiencing headaches.  
Resolution of Adverse Event: Subject voluntarily withdrew from the study, and the symptoms resolved.  
Relationship to Test Material: Possibly related  
Date of Adverse Event Onset: 01/07/2010  
Date of Adverse Event Resolution: 01/24/2010

**SUBJECT DEMOGRAPHICS**

Sixteen (16) female subjects completed study participation. Table 1 lists each subject's ethnicity and date of birth. Ethnicity information was obtained from each subject's Eligibility and Health Questionnaire.

**TABLE 1  
 SUBJECT DEMOGRAPHICS**

Subject Number	Ethnicity	Date of Birth	Subject Number	Ethnicity	Date of Birth
001	Caucasian	01-16-1978	010	African American	07-31-1963
002	Asian - Cambodian	04-14-1980	011	Caucasian	03-16-1984
003	Caucasian	03-27-1981	013	Caucasian	07-26-1972
004	Caucasian	08-20-1969	014	Hispanic - Mexican/Spanish	12-09-1978
005	Caucasian	02-18-1984	015	Caucasian	07-27-1983
006	Caucasian	01-14-1970	016	Caucasian	08-28-1976
007	Caucasian	12-28-1975	017	Hispanic - Mexican	09-15-1961
008	Asian - Chinese	07-24-1962	019	Filipino/Mexican	03-17-1974

The following contains a summary of the demographic information. For ethnicity, the number of subjects in each category is listed, followed by the percentage of the subject sample in parentheses.

		All Subjects (n=16)	
Age (Years)	Mean Age ± Standard Deviation	35.18 ± 7.56	
	Minimum Age	25.80	
	Maximum Age	48.31	
Ethnicity	African American	1 (6.3%)	
	Asian	Cambodian	1 (6.3%)
		Chinese	1 (6.3%)
	Caucasian	10 (62.5%)	
	Mexican	1 (6.3%)	
	Mixed Ethnicities	Filipino/Mexican	1 (6.3%)
		Mexican/Spanish	1 (6.3%)

**PROTOCOL AMENDMENT**

Affected Section of Protocol: Visit Time Points  
 Protocol Specification: Study procedures will be conducted at Baseline, Week 4, and Week 8.  
 Revised Wording: Study procedures will be conducted at Baseline, Week 4, and Week 10.  
 Reason of Revision: Sponsor requested to change the final visit from Week 8 to Week 10.

## **PROCEDURES AND METHODS**

At Baseline (Visit 1), each prospective subject read and signed a Confidentiality Agreement, a HIPAA Agreement, an Informed Consent Agreement, and a Photography Release Form. Subjects arrived at the clinic having refrained from washing the hair at least 24 hours prior to the visit.

Prospective subjects were examined on the scalp. Subjects who were free of alopecia and scalp disorders that were unacceptable for study participation completed an Eligibility and Health Questionnaire. Qualified subjects had their hair washed by clinic staff with shampoo over a sink containing cheesecloth. The cheesecloth was positioned to collect shedding hair. The number of hairs collected in the cheesecloth were counted and recorded. Subjects were permitted to dry and style their hair.

Each subject received a unit of the test material (containing 60 tablets per unit), a daily diary to record test material usage and any comments, a calendar of future visits, and the following written and verbal usage instructions:

### Usage Instructions:

Take two tablets a day (one in the morning and one in the evening) with water, after eating.

### Lifestyle Instructions:

Subjects were required to maintain their normal hair care routine. They were instructed to use the same brand/type of hair care products for the duration of the study. Subjects were not permitted to wear tight fitting hats or use tight fitting hair restraint items (i.e., rubber bands) during the study. Subjects were instructed to use a medically sound form of birth control during the study.

Subjects returned to the clinic at Week 4 (Visit 2) and Week 10 (Visit 3) having refrained from washing the hair at least 24 hours prior to each visit. Subjects were interviewed to assess any changes in their health. The completed daily diaries were returned, and new daily diaries were distributed at Week 4. The completed daily diaries were reviewed for compliance, and any discrepancies were clarified with the subject at that time. The test materials were collected and examined for compliance. Each subject's test material unit was re-distributed, along with a new unit of test material (containing 60 tablets) at Week 4.

At Week 4 and Week 10, subjects had their hair washed by clinic staff with shampoo over a sink containing cheesecloth. The cheesecloth was positioned to collect shedding hair. The number of hairs collected in the cheesecloth were counted and recorded. Subjects were permitted to dry and style their hair. Upon completion of the procedures, subjects completed Self-Assessment Questionnaires regarding the health of their hair.

## BIostatistics and Data Management

Mean hair counts at Week 4 (Visit 2) and Week 10 (Visit 3) were statistically compared to mean Baseline (Visit 1) scores using a paired t-test. Changes from Baseline were considered significant at the  $p \leq 0.05$  level. Mean percent change from Baseline and incidence of positive responders were calculated for all attributes. (Please see Appendix I for complete statistical calculations.)

The Self-Assessment Questionnaires were tabulated and a top-box/bottom-box analysis was conducted. (Please see Appendix II for the questionnaire analysis.)

Electronic data capture (EDC) methods were used for all hair counts. Paper copies were not generated for items captured in EDC. The Stephens EDC system is a computerized system designed for the collection of clinical data in electronic format. The three major aspects of EDC are 1) a graphical user interface for data entry, 2) a validation component to check for user data, and 3) a reporting tool for analysis of the collected data. Statistical analyses are performed using SAS software version 7.10 version 9 series (SAS Statistical Institute).

The Stephens EDC is compliant with the Food and Drug Administration (FDA) regulations, namely the FDA's 21 Code of Federal Regulations Part 11 regulation "Electronic Records; Electronic Signatures", which regulates the use of EDC in trials. A content validation study was performed to ensure that the Stephens EDC system has adequate coverage of all the critical EDC system features.

## Maintenance of Records

All original records (including the study protocol, clinical grading records, medical histories, informed consent agreements, attrition form, and any other records or forms used in this study), along with a copy of the final report, will be retained on file in the Thomas J. Stephens & Associates archives for two years from the date of study completion. When the archive time has expired, the Sponsor will be contacted to determine if the study files will be forwarded to the Sponsor or destroyed.

## Results

At Baseline (Visit 1), Week 4 (Visit 2), and Week 10 (Visit 3), subjects had their hair washed by clinic staff with shampoo over a sink containing cheesecloth. The number of hairs collected in the cheesecloth were counted and recorded. Table 2 presents the mean values. Mean values at each post-baseline time point were statistically compared to mean Baseline values for significant differences. The average percent change (% change) is listed in parentheses.(n=number of subjects).

**TABLE 2**  
**MEAN VALUES OF HAIR COUNTS (n=16)**

	Baseline	Week 4		Week 10	
	Mean	Mean	% Change	Mean	% Change
Hair Counts	69.13	61.00	(-11.7%)	37.00	(-46.4%)

**RESULTS (continued)**

At Week 4 (Visit 2) and Week 10 (Visit 3), subjects completed Self-Assessment Questionnaires regarding the health of their hair. Table 3 presents the results. The number of subjects is listed, followed by the percentage of the total subject sample in parentheses.

**TABLE 3  
 RESULTS OF SELF-ASSESSMENT QUESTIONNAIRES (n=16)**

\* Indicates a greater proportion of subjects responded favorably than unfavorably

		Greatly Increased; Moderately Increased; Slightly Increased	Greatly Decreased; Moderately Decreased; Slightly Decreased
1. Overall hair volume	Week 4	*15 (93.7%)	0 (0.0%)
	Week 10	*12 (75.0%)	0 (0.0%)
2. Scalp coverage	Week 4	*9 (56.2%)	1 (6.2%)
	Week 10	*10 (62.5%)	0 (0.0%)
3. Thickness of hair body	Week 4	*11 (68.7%)	1 (6.2%)
	Week 10	*12 (75.0%)	0 (0.0%)
4. Softness of hair body	Week 4	*11 (68.7%)	0 (0.0%)
	Week 10	*9 (56.2%)	1 (6.2%)
5. Hair shine	Week 4	*11 (68.7%)	0 (0.0%)
	Week 10	*9 (56.2%)	1 (6.2%)
6. Hair shedding on average day	Week 4	*11 (68.7%)	2 (12.5%)
	Week 10	*13 (81.2%)	1 (6.2%)
7. Nail strength	Week 4	*11 (68.7%)	0 (0.0%)
	Week 10	*13 (81.2%)	0 (0.0%)
8. Nail growth rate	Week 4	*8 (50.0%)	0 (0.0%)
	Week 10	*14 (87.5%)	0 (0.0%)
9. Overall skin health	Week 4	*11 (68.7%)	0 (0.0%)
	Week 10	*10 (62.5%)	0 (0.0%)

## **DISCUSSION AND CONCLUSIONS**

This pilot consumer research study was conducted for Life's 2 Good to evaluate the overall acceptability of a Viviscal supplement in female subjects with self-perceived thinning hair associated with poor diet, stress, hormonal influences, or abnormal menstrual cycles. Sixteen (16) female subjects with self-perceived thinning hair associated with poor diet, stress, hormonal influences, or abnormal menstrual cycles completed the study.

A summary of the results is presented below:

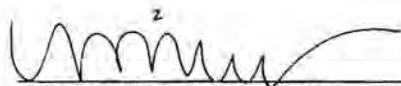
- Hair Counts:  
Results of the hair counts showed that there were no significant differences at any time point, when compared to Baseline.
  
- Self-Assessment Questionnaires:  
The top-box/bottom-box analysis showed that a greater proportion of the subjects responded favorably than unfavorably for all parameters at Week 4 and Week 10.

Results show that Life's 2 Good's Viviscal supplement was well received by test subjects. Analyses of hair counts showed a directional reduction in hair shedding over the 10 week period. A greater proportion of subjects responded favorably than unfavorably to questionnaires about improved hair volume, better scalp coverage, improved thickness of hair body, improved softness, improved hair shine, reduced hair shedding, improved nail strength and growth rate and overall skin health.

### STATEMENT OF QUALITY ASSURANCE

All data and supporting documentation for this study have been audited by the Thomas J. Stephens & Associates, Inc. Quality Assurance Department and found to be accurate, complete, and in compliance with the requirements of the protocol and Thomas J. Stephens & Associates' Standard Operating Procedures. This report has been reviewed and accurately reflects all aspects of the conduct of the study.

All clinical research studies that are performed by Thomas J. Stephens & Associates are in accordance with federal regulations and Good Clinical Practice guidelines.



Monae Miller, MHA, CCRC  
Quality Assurance Manager

5/11/10  
Date

### REPORT APPROVAL

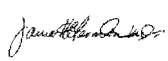
Report approved by:

THOMAS J. STEPHENS & ASSOCIATES, INC.

Thomas J. Stephens Digitally signed by Thomas J. Stephens  
DN: cn=Thomas J. Stephens, o=Thomas J.  
Stephens & Associates, Inc., ou=President,  
email=stephens@stephens-associates.com,  
c=US  
Date: 2010.05.05 10:42:47 -0500

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Thomas J. Stephens, Ph.D. Date  
Investigator

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James H. Herndon, Jr., M.D., FAAD, Date  
Board Certified Dermatologist  
Sub-Investigator/Study Physician

## **APPENDICES**

- I. Biostatistics**
- II. Questionnaire Analysis**
- III. Protocol: An 10-Week Pilot Consumer Perception Test to Evaluate the Overall Acceptability of a Viviscal Oral Supplement When Used by Females with Self-Perceived Thinning Hair**
- IV. Sample Forms**
  - Eligibility and Health Questionnaire
  - Informed Consent Agreement
  - HIPAA Agreement
  - Confidentiality Agreement - Photography Release Form
- V. Copy of Attrition Form**
- VI. Copy of Adverse Event Form**
- VII. Copies of Self-Assessment Questionnaires**