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Executive Summary

Prospective, Randomized, Placebo-Controlled Clinical Trial to Test the Efficacy and Short-Term Safety of Sunset Health's 'Hollywood Diet', a Dietary Supplement Drink, Designed for Short-Term Weight Loss and Cleansing

This trial has received Institutional Review Board (IRB) Approval

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Clinical Site:

Bangor, Maine:
Marshall-Blum: Clinical Outcomes Specialists (parent company)
Herbal Research Clinic
Independent Medical Research Center
James M. Blum, PhD, Study Coordinator, Epidemiologist and Biostatistician
Medical Director: Ronald I. Blum, MD
Medical Advisor: Felix Hernandez, MD

Protocol

Design:

- Prospective, randomized, double-blind, placebo-based, clinical trial
- This trial had IRB approval (due to FDA guidelines, details are only available upon request)
- Randomization determined who started on placebo and who started with the active product; randomization between groups were of equal numbers
- The duration was for two days on either product or placebo; subjects were observed for a total of seven days
- All subject contact was with a study coordinator or research nurse who were blinded to the randomization scheme
- Subjects adhered to the diet and exercise requirements in the consent form/protocol, which were reviewed by one of the nurses during the enrollment period
- Subjects were recruited from the general population of Bangor, Maine; the major exclusion criteria were pregnant or nursing women, co-morbid conditions that might place an individual at risk with this type of product, alcohol use of any kind during the trial period, and insulin-dependent diabetes mellitus (IDDM)

Product Usage and Subject Instructions:

Take 4 servings daily for two days; 1 serving in the morning, 1 serving at noon, 1 serving in the late afternoon, and 1 serving in the evening. For each serving, mix 4 ounces of your assigned product with 4 ounces of water and sip it over 4 hours.

In addition, **drink 8-eight ounces glasses of water per day, for a total of 64 ounces per day.**

Otherwise, **fast for the two-day period.**

- **You will need to return to the clinic 2 times after receiving your assigned product.** Please return to the clinic before you eat anything the morning after you complete the second day of taking your assigned product (Day 4). Return to the

clinic again for a 7-Day visit. The questionnaires will be reviewed at this time. Measurements will be taken. Additional information will be handed out and questions will be answered at each visit.

- **Please report any difficulties with the assigned product or ask any questions that you have as soon as possible.**

- **Please inform us of any change in your health status or medications immediately.** Someone will be available around-the-clock to pick up messages.

- Bring your assigned product bottle and Exercise Log with you for your 4-Day visit.

Exercise:

Try to do some modest exercise to burn off excess energy and help your body's natural peristalsis (digestive and elimination process) begin to work efficiently.

Alcohol, Caffeine, and Nicotine:

Do NOT consume any alcohol or use any nicotine for the two days that you are fasting and taking your assigned product. It is best NOT to consume any caffeine either, but if you normally consume moderate to large amounts of caffeine on a daily basis, you may consume up to 2 cups of black coffee per day to avoid withdrawal symptoms. DO NOT consume any other form of caffeine or add anything to your coffee.

Placebo Product

The placebo was similar in appearance (amount, texture, color) to the actual product except that it only contained inactive rice powder-based materials.

Inclusion Criteria:

- Subjects wishing to learn to manage their weight and/or cleanse their systems; subjects who answer an advertisement announcing this trial
- Ages: 18-70
- BMI > 27
- Subjects who passed a compliance screening test
- Subjects able to tolerate the active product and placebo
- Subjects who signed a consent form

Exclusion Criteria:

- Subjects who are non-compliant with testing and taking treatment regimens
- Subjects under 18 or over the age of 70
- Subjects who are pregnant, nursing, or actively trying to become pregnant
- Subjects with moderately severe co-morbid disease, that includes cardiac, pulmonary, renal, hepatic, or active cancer (this determination is subject to the study physician)
- Subjects with insulin-dependent diabetes
- Subjects who use alcohol during the trial or who have a history of alcohol abuse as determined by provider interviews or medical history
- Subjects who are non-compliant with testing and taking treatment regimens
- Subjects unable to tolerate specific ingredients in either regimen
- Subjects on medications or other herbal preparations for the treatment of weight management or cholesterol control

Cautionary Criteria (as specified by the IRB):

Subjects with the following conditions should be carefully considered:

- High caffeine intake
- Allergies to ragweed
- Asthma
- Bipolar disorders
- Bleed easily
- Depression
- Diabetes
- Difficulty in urination due to prostate enlargement
- Glaucoma
- Kidney disease
- Liver disease
- Taking a MAO inhibitor
- Thyroid disease

Co-Morbid Disease Cautions:

- Renal insufficiency: baseline serum creatinine greater or equal to (g.e.) 1.6 or on dialysis
- Ischemic Heart Disease (See Details Below for Definitions):
- Valvular Heart Disease: 2+ or greater aortic, mitral, tricuspid, or pulmonary valve involvement
- Treatment for Hypertension: any standard medications for the treatment of hypertension
- Peripheral Vascular Disease: carotid bruits, femoral, pedal, or other type diagnosis
- Pulmonary Disease: COPD, treated asthma or emphzema
- Diabetes mellitus: controlled by oral agents or insulin

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- Neuromuscular Disease
- Prior Stroke, TIA, RIND, or other similar conditions
- Cancer: either history or current

Ischemic Heart Disease:

- Prior Revascularization Procedures (Angioplasty, Stents, Coronary Artery Bypass Grafting, or similar procedures)
- Positive Stress Test
- Current Medications that include: beta blockers, calcium channel blockers, or ace inhibitors
- Arrhythmias

Confounding Factors:

- Age
- Prior attempts at weight management
- Baseline weight or Body Mass Index

Primary End-Points

- Weight loss (pounds)
- Body Mass Index (BMI)

Other End-Points

- Blood pressures (systolic and diastolic)
- General Well-Being
- Recommend product

Analytical Methods

Weight Measurements

- All weights were made on a Health-O-Meter Professional unit, calibrated shortly before the study began.
- Subjects were asked to take off all clothes except underwear and socks and put on a gown. A few subjects refused but agreed to wear the same identical clothes (baseline and post-treatment).
- Subjects were requested to drink eight glasses of water several times per day throughout the trial, including prior to weigh-ins.

Statistical Significance

These criteria were set prior to the analysis.

Highly Significant: $p < 0.05$

Significant: $p < 0.10$

Statistical Trend: $p < 0.15$

Randomized, Placebo-Controlled Clinical Trial Results

Subject Numbers

A total of sixty-four subjects were initially screened and randomized into both arms of the study. Thirty (30) subjects completed the product phase of this trial while the same number (thirty) individuals completed the placebo phase of this trial.

Baseline Characteristics

There was only one major risk factor, and only a few minor differences in the baseline characteristics between the two groups (treatment and placebo) that included approximately seventy-five variables. The baseline variables included demographics (age, gender, weight, height, body mass index), medical risk (diabetes, hypertension, cardiac, gastrointestinal, cancer, etc.), behavioral (caffeine intake, alcohol consumption, smoking profiles), and social-economic parameters (income, jobs, education, etc.).

Depression was the only major factor that was different at the 0.05 level (26.7 in the product group compared to 6.7 in the placebo group, $p< 0.04$). Differences occurred in the number of current smokers (33.3% v. 7.2%, product v. placebo, $p<0.014$), teachers/students (13.3 v. 32.1, $p<0.086$), income of $60k or greater (6.6 v. 21.4, $p<0.14$), and regularly use vitamins or herbal supplements (see Table with Baseline data).

Difference of Means

The mean weight loss in the treatment group was 7.46, compared to a loss of 4.34 pounds in the placebo group. This difference was highly statistically different at the 0.0001 level. The weight loss variance was nearly identical.

Categorically, there were major differences between the two groups. For those subjects who lost more than six (6) pounds or more, twenty-two (22) came from the treatment group (73.3%), while only three (3) were from the placebo group ($p < 0.0001$). For those losing ten or more pounds, all four (4, 13.3%) were from the treatment group ($p < 0.11$ Fisher's Exact Chi-Square)

"Soft" End-Points

When asked about their general well-being and energy levels after the two-day diet, nearly three-quarters (73%) of those on product responded positively. Additionally, many of the individual statements were quite favorable in this aspect.

In the treatment group, eighty percent said they would recommend the Hollywood Diet to a friend.

Adverse Events

There were no major adverse events reported in this trial. A total of twelve (12) subjects, seven (7) from the product group and five (5) from the placebo group reported a series of relatively minor concerns. Two individuals in both groups (n=4) reported minor gastrointestinal upsets (cramping, nausea), two subjects in both groups (n=4) reported headaches, one subject in both groups reported dizziness, while one subject each reported fatigue and dry mouth.

Conclusions

The baseline characteristics were essentially the same between the product and placebo groups. There were two (2) statistical differences among approximately eighty (80) variables for a rate approaching two and half percent (2.5%). It would be expected due to chance alone that five percent would be different. This shows that the randomization worked effectively and does not contribute to any selection biases that might cloud these results.

This short duration randomized, placebo-based clinical trial clearly shows that 'The Hollywood Diet' is effective in delivering 'weight loss', and general well-being. All these parameters were statistically significant between those subjects taking the product and those taking a suitable placebo.

A major possible confounder was avoided by the rigorous intake of water throughout the study period (approximately eight glasses of water per day) and by accurate weighing techniques.

There were no reports of serious adverse events among the sixty-four who started the trial. We did have some reports of minor complaints, but all resolved by the seventh day.

Within the parameters of this trial, the Hollywood Diet is an effective and safe approach to cleansing and quick weight loss.

Diet (SUNSET) Intake Form
Marshall-Blum LLC

Date: 3/31/03   ID#: ▮▮▮▮

ALL SUBJECTS:

Initial Visit:	SUNSET1	4/1/03	Time: 7:15
1-Day Visit:	SUNSET2	4/1/03	Time: 6:00 (approx. 6pm to 7pm)
4-Day Visit:	SUNSET3	4/4/03	Time: 7:15 (approx. 7am to 8am)
7-Day Visit:	SUNSET4	4/7/03	Time: 7:00

Signed Photo Release: 0. ☒ No   1. ☐ Yes

(Compensation:) $_____.00 paid __/__/__ check # _____.   Initials _____

_____1_____ bottle(s) of product.   Initials HDG

END OF STUDY – NO FURTHER DATA REQUIRED – NO CROSSOVER

First Name: ____▮▮▮▮____ Middle Initial: _____ Last Name: ____▮▮▮▮____

Mailing Address: ____▮▮▮▮____

City: ____▮▮▮▮____ State: _____ Zip Code: _____

Phone: (___) ▮▮▮▮   Phone: (___) ____-____

Is it okay to leave a message?   0. ☐ No   1. ☒ Yes

Email: _____   Age: 37 (18-55)

Height: 5'3"   Weight: 200 lbs.   Estimated BMI: 35 (33-40)

BMI qualification (see Body Mass Index Qualifying Chart):   0. ☐ No (exclusionary)   1. ☒ Yes

Are you insulin dependent diabetic: 0. ☒ No   1. ☐ Yes (exclusionary)

Do you have uncontrolled high blood pressure: 0. ☒ No   1. ☐ Yes (exclusionary)

Are you nursing, pregnant, or trying to become pregnant: 0. ☒ No   1. ☐ Yes (exclusionary)

Do you have chronic diarrhea or loose stools: 0. ☒ No   1. ☐ Yes (exclusionary)

Do you have chronic abdominal pain: 0. ☒ No   1. ☐ Yes (exclusionary)

Continued on back

Have you taken any medications or dietary supplements
for weight loss within the past 30 days: 0. ☒No   1. ☐ Yes (wait period)

Do you have any major medical conditions: 0. ☒No   1. ☐ Yes (nurse review)
(H/O stroke, cancer, kidney disease, liver disease)

Usual Caffeine Intake ___2___ (cups/day)
Are you willing to restrict caffeine intake for this trial: 0. ☐ No (exclusionary)   1.☒Yes
                                                                      2. ☐ N/A

Usual Alcohol Intake ___0___ (≤6 drinks/week)
Are you willing to stop all alcohol intake for this trial: 0. ☐ No (exclusionary)   1. ☐ Yes
                                                                    2.☒N/A

Usual Nicotine Use ___0___ (cigarette packs/day equivalent)
Are you willing to stop all nicotine use for this trial: 0. ☐ No (exclusionary)   1. ☐ Yes
                                                                  2.☒N/A

Current Medications: ___*Celexa (depression - 2yrs)*___

Exclusionary Meds: warfarin (coumadin), heparin, levodopa, >2 aspirin per day or any other blood thinning
medications, calcium channel-blockers, dilantin, digoxin or other prescribed cardiac glycosides, MAO Inhibitors.
Nurse will evaluate others.

Health Concerns/Comments: _____

How did you hear about this clinical trial: ___*Radio*___
Trial length: 7 days (2 days on assigned product). Clinic Visits: Initial, 1-day, 4-day and 7-day. Ingredients:
Purified water, pineapple juice concentration, apple juice concentration, orange juice concentration, apricot puree,
peach puree, banana puree, vitamin A, beta carotene, vitamin C, calcium, iron, sodium, thiamine (B1), riboflavin
(B2), niacin (B3), pantothenic acid (B5), pyridoxine (B6), folic acid (B9), cobalamin (B12), vitamin D and vitamin
E. Randomization: 1:1. 50% chance of being on active product. Some possible side effects: Abdominal
cramping, anemia, bright yellow urine, constipation, diarrhea, dry mouth, false-positive for diabetes, fatigue,
flushing, headache, increased urination, loss of appetite, metallic taste, nausea, stomach pain, thirst, vomiting and
weakness.

Special Instructions:
1. Time Commitment
   • Initial visit   SUNSET1   45 minutes
   • 1-Day visit   SUNSET2   30 minutes at night after their evening meal (6pm to 7pm)
   • 4-Day visit   SUNSET3   30 minutes in the morning before eating or drinking
                                                           (7am to 8am)
   • 7-Day visit   SUNSET4   30 minutes
2. Compensation
   • All subjects who complete all of the study visits and requirements will receive 1 free bottle of the
     active product and $50.00 in compensation.

END

Demographic Form
Marshall-Blum, LLC

Study: ███████████████

Date: 4 / 1 / 03   ID#: ██████

This survey asks you general demographic questions. It is intended to give us a snapshot of the population that is in this study. All information is strictly confidential and is presented in a cumulative summarized form. We greatly appreciate your help and cooperation in this matter.

Please answer every question by marking one box. If you are unsure about an answer, please give the best answer you can. If you feel uncomfortable answering a question, please skip that question and move to the next one.

1. Please select the appropriate gender category: 1. ☐ Male   2. ☑ Female

2. Your current age is: __36__ years

3. Please select your ethnic origin:
1. ☐ Asian or Pacific Islander   4. ☐ Native American or Alaskan Native
2. ☐ Black   5. ☑ White
3. ☐ Hispanic   6. ☐ Other, please specify: _____

4. Your current weight is approximately: __202__ pounds

5. Your height is approximately: (feet and inches): __5__ ft / __3__ inches

6. Please indicate the category that best describes your current occupation/homemaking status:
1. ☐ clerical   2. ☐ craftsperson/technical   3. ☐ homemaker   4. ☐ management
5. ☐ military   6. ☑ professional   7. ☐ retired   8. ☐ self-employed
9. ☐ service industry 10. ☐ student   11. ☐ teaching   12. ☐ not working
12. ☐ Details or Other, please specify: _____

7. In the above mentioned jobs / duties, do you work:
1. ☑ 36 hours or More
2. ☐ Less than 36 hours
3. ☐ Not Applicable

8. Please indicate the category that best represents your total annual household income (all sources), before taxes:
1. ☐ Under $20,000   4. ☐ $60,000 and under $80,0000
2. ☐ $20,000 and under $40,000   5. ☐ $80,000 and under $100,000
3. ☑ $40,000 and under $60,000   6. ☐ $100,000 and above

Continued on back

9. Including yourself, how many adults live in your household (18 years old or Over)?

1. ☐ 1   2. ☑ 2   3. ☐ 3   4. ☐ 4   5. ☐ 5-6   6. ☐ 7 or more

10. How many people under 18 years old live in your household?

1. ☑ 0   2. ☐ 1   3. ☐ 2   4. ☐ 3   5. ☐ 4   6. ☐ 5 or more

11. Please indicate the highest level of education that you have achieved?

1. ☐ Did not graduate from High School
2. ☐ Graduated High School
3. ☐ Some college or vocational training or Associate Degree
4. ☑ Bachelor Degree and/or Some-Post-Graduate
5. ☐ Graduate Degree
6. ☐ Doctorate or Professional Degree

12. Please indicate your current smoking status?

0. ☑ I have never smoked
1. ☐ No, I quit in the last two years
2. ☐ No, I quit more than two years ago
3. ☐ Yes, I smoke less than 1 pack a day
4. ☐ Yes, I smoke one pack or more a day

13. If an alcoholic drink is defined as: one bottle/can of beer _equals_ one glass of wine _equals_ one ounce of hard liquor, _how may drinks do you consume in an average week:_

0. ☐ None   1. ☑ average less than 1   2. ☐ 1- 2   3. ☐ 3-4   4. ☐ 5-6   5. ☐ 7-8
6. ☐ 9-10   7. ☐ more than 10

14. How many times each week do you exercise?

1. ☑ Less than 1   2. ☐ 1-2   3. ☐ 3-4   4. ☐ 5-6
5. ☐ 7-8   6. ☐ 9 or more

15. In general, would you say your health is:

1. ☐ Excellent   2. ☐ Very Good   3. ☐ Good   4. ☑ Fair   5. ☐ Poor

16. Do you use vitamin supplements?

1. ☐ Yes   0. ☐ No   2. ☑ Sometimes

17. Do you use herbal supplements?

1. ☐ Yes   0. ☐ No   2. ☑ Sometimes

18. Do you use any non-physician practitioners for your medical care?

1. ☐ Yes   0. ☑ No   2. ☐ Sometimes

END – Thank you for your participation

Diet (SUNSET) Initial Visit Form
Marshall-Blum LLC

Date: 4 / 1 / 03   ID#: ▮▮▮▮

Visit: <u>Baseline</u>

Your Medical History (please mark a box for each condition and describe if you mark "Yes"):

			Condition	Description
1.	0. ☑ No	1. ☐ Yes	Diabetes	
2.	0. ☑ No	1. ☐ Yes	High Blood Pressure	
3.	0. ☑ No	1. ☐ Yes	Thyroid Disease	
4.	0. ☑ No	1. ☐ Yes	Asthma	
5.	0. ☑ No	1. ☐ Yes	COPD (Lung Disease)	
6.	0. ☑ No	1. ☐ Yes	Heart Disease	
7.	0. ☐ No	1. ☑ Yes	Depression	Take celexa 20 mg daily
8.	0. ☑ No	1. ☐ Yes	Previous Injuries	
9.	0. ☐ No	1. ☑ Yes	Previous or Planned Surgeries	'96 Gallbladder. - lap
10.	0. ☑ No	1. ☐ Yes	Kidney Disease	
11.	0. ☑ No	1. ☐ Yes	Kidney Stones	
12.	0. ☐ No	1. ☑ Yes	Gallbladder Attack	yes- removal 1996.
13.	0. ☐ No	1. ☑ Yes	Gallstones	Removed
14.	0. ☑ No	1. ☐ Yes	Liver Disease	
15.	0. ☑ No	1. ☐ Yes	Bowel Disease	
16.	0. ☑ No	1. ☐ Yes	Ulcer or Stomach Disease	
17.	0. ☑ No	1. ☐ Yes	Any Cancer	

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Marshall-Blum LLC   01/30/03

	Condition	Description
18. 0. ☑ No 1. ☐ Yes	High Cholesterol	
19. 0. ☑ No 1. ☐ Yes	Osteoarthritis	
20. 0. ☑ No 1. ☐ Yes	Rheumatoid Arthritis	
21. 0. ☑ No 1. ☐ Yes	Epilepsy	
22. 0. ☑ No 1. ☐ Yes	Convulsions	
23. 0. ☑ No 1. ☐ Yes	Seizures	
24. 0. ☑ No 1. ☐ Yes	Hemophilia (a bleeding disorder)	
25. 0. ☑ No 1. ☐ Yes	Gout	
26. 0. ☐ No 1. ☑ Yes	Migraines	Very rarely
27. 0. ☑ No 1. ☐ Yes	Any Diet Restrictions	
28. 0. ☑ No 1. ☐ Yes	Other	

29. Medicines: Celexa 20mg daily 2 yrs

30. Dietary Supplements: ∅

31. Alternative Therapies: ∅

32. Allergies: Drug allergies - Erythin - θ to Sulfa -

33. Some testing equipment contains latex. Do you have an allergy to latex?

    0. ☑ No   1. ☐ Yes   2. ☐ Uncertain

Continued on next page

Visual Analogue Rating Scales

Please mark on the line how you have felt over the past week.

46. *Average* amount of energy

None |————————————————|————| High

47. *Highest* amount of energy

None |————————————————————|——| High

48. Generally speaking, how many hours per day do you experience this highest level of energy?

    0. ❏ 0-0.5 hours   1. ❏ 0.5-1 hours   2. ☑ 1-2 hours
    3. ☑ 2-3 hours   4. ❏ 3-4 hours   5. ❏ more than 4 hours

49. *Average* amount of general fatigue

None |————|————————————————| Severe

50. *Highest* amount of general fatigue

None |————|————————————————| Severe

Quality of Life Questions

Questions 51 - 54 are about how you feel and how things have been with you <u>during the past week</u>. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past week**:

51. Have you felt calm and peaceful?

    0. ❏ None of the time   1. ❏ A little of the time   2. ❏ Some of the time
    3. ❏ A good bit of the time   4. ☑ Most of the time   5. ❏ All of the time

52. Did you have a lot of energy?

    0. ❏ None of the time   1. ❏ A little of the time   2. ☑ Some of the time
    3. ❏ A good bit of the time   4. ❏ Most of the time   5. ❏ All of the time

Continued on back

53. Have you felt downhearted and blue?

    0. ☑ None of the time   1. ☐ A little of the time   2. ☐ Some of the time
    3. ☐ A good bit of the time   4. ☐ Most of the time   5. ☐ All of the time

54. During the past week, how often have you taken pain medication, including narcotics or over-the-counter medications?

    0. ☑ None   1. ☐ 1   2. ☐ 2-4
    3. ☐ 5-7   4. ☐ 8-10   5. ☐ >10

55. Can we put you on a mailing list for other upcoming studies: 0. ☐ No   1. ☑ Yes

END – Thank you for your participation

Diet (SUNSET) Subject Evaluation Form
Marshall-Blum LLC

Date: _4/ 4 / 03_　　　　　　　　　　　　　　　ID#: ▮▮▮▮▮

Visit: 4-Day

1. How do you feel you have done with the fasting requirements over the last two days?

　　Did not Comply =　0　1　2　3　4　5　6　7　8　(9) = Totally Compliant

2. How do you feel you have done with the exercise requirements over the last two days?

　　Did not Comply = (0)　1　2　3　4　5　6　7　8　9　= Totally Compliant

3. How do you feel you have done with the supplement requirements over the last two days?

　　Did not Comply =　0　1　2　3　4　5　6　7　8　(9) = Totally Compliant

4. How do you feel you have done with the water consumption requirements over the last two days?

　　Did not Comply =　0　1　2　3　4　5　6　7　8　(9) = Totally Compliant

5. How much alcohol did you consume over the last two days? _Ø_ (number of standard drinks)

6. How much nicotine did you use over the last two days? _Ø_ (number of cigarettes or equivalent)

7. How much caffeine did you consume over the last two days? _4_ (number of standard cups)

　　If you consumed caffeine, please describe its amount and preparation: _Black coffee_
　　_2 on 4-2, 2 on 4-3._

8. Would you use this weight management system again?

　　0. ☐ No　　1. ☑ Yes　　2. ☐ Uncertain

9. Would you recommend this system to a friend?

　　0. ☐ No　　1. ☑ Yes　　2. ☐ Uncertain

10. Side Effects: _wt loss & feeling great!_

Continued on back

11. Unexpected Benefits: _____

_____

12. Comments: _____

_____

_____

13. In general, how do you feel now compared to before you took the assigned product?

A lot worse =   -4   -3   -2   -1   **0**   1   2   3   **④**   = A lot better

Same

General Questions

Please answer the following questions related to **how you have felt over the past two days**.

14. During the times when you **should** be fully rested, how often were you feeling tired?

0. ☐ None of the time   1. ☐ A little of the time   2. ☐ Some of the time
3. ☑ A good bit of the time   4. ☐ Most of the time   5. ☐ All of the time

15. Did you have trouble getting to sleep at night?

0. ☐ Never   1. ☑ Rarely   2. ☐ Sometimes   3. ☐ Frequently

16. On the average, how many times during the night did you wake up (please circle one)?

0   1   ②   3   4   5   6   7   8   9   10   > 10

17. How long did you sleep at night, on average?

0. ☐ 0-2 hours   1. ☐ 2-4 hours   2. ☐ 4-6 hours
3. ☑ 6-8 hours   4. ☐ 8-10 hours   5. ☐ 10-12 hours

18. Did you feel tired or sleepy during the day?

0. ☐ Never   1. ☑ Rarely   2. ☐ Sometimes   3. ☐ Frequently

Continued on the next page

Diet (SUNSET) End of Study Form
Marshall-Blum LLC

Date: 4/17/03   ID#: ▓▓▓▓▓

Visit: 7-Day

1. Would you use this weight management system again?

     0. ☐ No   1. ☑ Yes   2. ☐ Uncertain

2. Would you recommend this system to a friend?

     0. ☐ No   1. ☑ Yes   2. ☐ Uncertain

3. Side Effects: _____

_____

4. Unexpected Benefits: _I felt great, ~~fatigue~~ fatigue____

_____

5. Comments: _____

_____

_____

6. In general, how do you feel now compared to before you took the assigned product?

     A lot worse =   -4   -3   -2   -1   **0**   1   2   3   ④   = A lot better
                                              Same

General Questions

Please answer the following questions related to **how you have felt over the past two days.**

7. During the times when you **should** be fully rested, how often were you feeling tired?

     0. ☐ None of the time   1. ☑ A little of the time   2. ☐ Some of the time
     3. ☐ A good bit of the time   4. ☐ Most of the time   5. ☐ All of the time

Continued on back

8. Did you have trouble getting to sleep at night?

      0. ☑ Never   1. ☐ Rarely   2. ☐ Sometimes   3. ☐ Frequently

9. On the average, how many times during the night did you wake up (please circle one)?

      0 ① 2   3   4   5   6   7   8   9   10 > 10

10. How long did you sleep at night, on average?

      0. ☐ 0-2 hours   1. ☐ 2-4 hours   2. ☐ 4-6 hours
      3. ☑ 6-8 hours   4. ☐ 8-10 hours   5. ☐ 10-12 hours

11. Did you feel tired or sleepy during the day?

      0. ☐ Never   1. ☑ Rarely   2. ☐ Sometimes   3. ☐ Frequently

Visual Analogue Rating Scales

Please mark on the line how you have felt over the past two days.

12. *Average* amount of energy

None |———————————————|————————| **High**

13. *Highest* amount of energy

None |————————————————————//———| **High**

14. Generally speaking, how many hours per day do you experience this highest level of energy?

      0. ☐ 0-0.5 hours   1. ☑ 0.5-1 hours   2. ☐ 1-2 hours
      3. ☐ 2-3 hours   4. ☐ 3-4 hours   5. ☐ more than 4 hours

15. *Average* amount of general fatigue

None |—————————————//—————————————| **Severe**

Continued on the next page

16. *Highest* amount of general fatigue

None |————————————————|————————————————| Severe

Quality of Life Questions

Questions 17 - 20 are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past week:**

17. Have you felt calm and peaceful?

        0. ☐ None of the time   1. ☐ A little of the time   2. ☐ Some of the time
        3. ☐ A good bit of the time   4. ☑ Most of the time   5. ☐ All of the time

18. Did you have a lot of energy?

        0. ☐ None of the time   1. ☐ A little of the time   2. ☐ Some of the time
        3. ☐ A good bit of the time   4. ☑ Most of the time   5. ☐ All of the time

19. Have you felt downhearted and blue?

        0. ☑ None of the time   1. ☐ A little of the time   2. ☐ Some of the time
        3. ☐ A good bit of the time   4. ☐ Most of the time   5. ☐ All of the time

20. During the past week, how often have you taken pain medication, including narcotics or over-the-counter medications?

        0. ☑ None   1. ☑ 1   2. ☐ 2-4
        3. ☐ 5-7   4. ☐ 8-10   5. ☐ >10

END -- Thank you for your participation

Diet (SUNSET) Nurse Evaluation Form
Marshall-Blum LLC

Start Date: 4/02/03   Measured height: 5 · 4¼"   ID# ■■■■

p̄ live appt on 4/01/03   36 yo ♀

Variable	Baseline	1-Day	4-Day	7-Day	Comments
Date (mm/dd/yy)	4/01/03	4/1/03	4/4/03	4/07/03	
Date & time of last meal	3/31/03 ~ 10 pm (popcorn)	630 pm.	7 am ·	8 pm 4/06/03	
Weight (lbs.)	205.8	209.0 ·	201.4	200.0	
Time weight taken	4/01/03 8 am	630 pm ·	7 am	7²⁵ am	
Blood pressure: Cuff S / L (right arm unless otherwise specified)	120/88 Ⓡ A	128/80	124/81 ·	116/76	
Pulse (bpm)	72	76	78	72	
Respirations (rpm)	12	16 ·	14	16	
Photo taken	■■■	Yes / No	Yes / No	■■■	
Photo number(s) (if applicable)		Signature & delivery			
Comments	LMP ~ 3/08/03 IUD 2/14/03		Completed diet 5 problems.	has cold – started 4 d ago	

End

T-Test

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
Age	0	28	34.89	11.861	2.242
	1	30	34.83	11.774	2.150

Independent Samples Test

		Levene's Test for Equality of Variances	
		F	Sig.
Age	Equal variances assumed	.323	.572
	Equal variances not assumed		

Independent Samples Test

		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
Age	Equal variances assumed	.019	56	.985	.06
	Equal variances not assumed	.019	55.665	.985	.06

Independent Samples Test

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
Age	Equal variances assumed	3.105	-6.160	6.279
	Equal variances not assumed	3.106	-6.163	6.282

T-Test

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
BMI	0	28	33.4898	4.39701	.83096
	1	28	32.1183	4.93248	.93215

Independent Samples Test

		Levene's Test for Equality of Variances	
		F	Sig.
BMI	Equal variances assumed	.200	.657
	Equal variances not assumed		

		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
BMI	Equal variances assumed	1.098	54	.277	1.3715
	Equal variances not assumed	1.098	53.302	.277	1.3715

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
BMI	Equal variances assumed	1.24876	-1.13215	3.87507
	Equal variances not assumed	1.24876	-1.13290	3.87582

T-Test

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
Age	0	28	34.89	11.861	2.242
	1	30	34.83	11.774	2.150

Independent Samples Test

		Levene's Test for Equality of Variances	
		F	Sig.
Age	Equal variances assumed	.323	.572
	Equal variances not assumed		

Crosstabs

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Age * Prod	58	96.7%	2	3.3%	60	100.0%

Age * Prod Crosstabulation

Count

		Prod		Total
		0	1	
Age	18	1	2	3
	19	2	1	3
	20	2	0	2
	21	1	0	1
	22	0	3	3
	23	1	0	1
	24	0	1	1
	25	1	0	1
	26	1	0	1
	27	1	1	2
	28	1	3	4
	29	1	0	1
	32	0	4	4
	33	0	2	2
	34	2	0	2
	35	0	1	1
	36	0	1	1
	37	0	1	1
	38	2	0	2
	39	0	1	1
	41	1	1	2
	42	3	2	5
	43	1	0	1
	45	1	0	1
	46	1	0	1
	47	1	0	1
	50	1	0	1
	51	1	0	1
	53	1	5	6
	56	1	0	1
	58	0	1	1
Total		28	30	58

Crosstabs

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
Gender * Prod	60	100.0%	0	.0%	60	100.0%

Gender * Prod Crosstabulation

			Prod		Total
			0	1	
Gender	1	Count	3	5	8
		% within Gender	37.5%	62.5%	100.0%
		% within Prod	10.0%	16.7%	13.3%
	2	Count	27	25	52
		% within Gender	51.9%	48.1%	100.0%
		% within Prod	90.0%	83.3%	86.7%
Total		Count	30	30	60
		% within Gender	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Sugar1 * Prod Crosstabulation

			Prod		Total
			0	1	
Sugar1	0	Count	30	30	60
		% within Sugar1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within Sugar1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

BP1 * Prod Crosstabulation

			Prod		Total
			0	1	
BP1	0	Count	28	29	57
		% within BP1	49.1%	50.9%	100.0%
		% within Prod	93.3%	96.7%	95.0%
	1	Count	2	1	3
		% within BP1	66.7%	33.3%	100.0%
		% within Prod	6.7%	3.3%	5.0%
Total		Count	30	30	60
		% within BP1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Thy1 * Prod Crosstabulation

			Prod		Total
			0	1	
Thy1	0	Count	29	29	58
		% within Thy1	50.0%	50.0%	100.0%
		% within Prod	96.7%	96.7%	96.7%
	1	Count	1	1	2
		% within Thy1	50.0%	50.0%	100.0%
		% within Prod	3.3%	3.3%	3.3%
Total		Count	30	30	60
		% within Thy1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Asth1 * Prod Crosstabulation

			Prod		Total
			0	1	
Asth1	0	Count	26	28	54
		% within Asth1	48.1%	51.9%	100.0%
		% within Prod	86.7%	93.3%	90.0%
	1	Count	4	2	6
		% within Asth1	66.7%	33.3%	100.0%
		% within Prod	13.3%	6.7%	10.0%
Total		Count	30	30	60
		% within Asth1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

COPD1 * Prod Crosstabulation

			Prod		Total
			0	1	
COPD1	0	Count	30	30	60
		% within COPD1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within COPD1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

heart1 * Prod Crosstabulation

			Prod		Total
			0	1	
heart1	0	Count	30	30	60
		% within heart1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within heart1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Depr1 * Prod Crosstabulation

			Prod		Total
			0	1	
Depr1	0	Count	28	22	50
		% within Depr1	56.0%	44.0%	100.0%
		% within Prod	93.3%	73.3%	83.3%
	1	Count	2	8	10
		% within Depr1	20.0%	80.0%	100.0%
		% within Prod	6.7%	26.7%	16.7%
Total		Count	30	30	60
		% within Depr1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Injur1 * Prod Crosstabulation

			Prod		Total
			0	1	
Injur1	0	Count	26	26	52
		% within Injur1	50.0%	50.0%	100.0%
		% within Prod	86.7%	86.7%	86.7%
	1	Count	4	4	8
		% within Injur1	50.0%	50.0%	100.0%
		% within Prod	13.3%	13.3%	13.3%
Total		Count	30	30	60
		% within Injur1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Surg1 * Prod Crosstabulation

			Prod		Total
			0	1	
Surg1	0	Count	20	24	44
		% within Surg1	45.5%	54.5%	100.0%
		% within Prod	66.7%	80.0%	73.3%
	1	Count	10	6	16
		% within Surg1	62.5%	37.5%	100.0%
		% within Prod	33.3%	20.0%	26.7%
Total		Count	30	30	60
		% within Surg1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Renal1 * Prod Crosstabulation

			Prod		Total
			0	1	
Renal1	0	Count	30	30	60
		% within Renal1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within Renal1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

StoneR1 * Prod Crosstabulation

			Prod		Total
			0	1	
StoneR1	0	Count	30	30	60
		% within StoneR1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within StoneR1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

GallAtt * Prod Crosstabulation

			Prod		Total
			0	1	
GallAtt	0	Count	29	29	58
		% within GallAtt	50.0%	50.0%	100.0%
		% within Prod	96.7%	96.7%	96.7%
	1	Count	1	1	2
		% within GallAtt	50.0%	50.0%	100.0%
		% within Prod	3.3%	3.3%	3.3%
Total		Count	30	30	60
		% within GallAtt	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

GallSto * Prod Crosstabulation

			Prod		Total
			0	1	
GallSto	0	Count	28	29	57
		% within GallSto	49.1%	50.9%	100.0%
		% within Prod	93.3%	96.7%	95.0%
	1	Count	2	1	3
		% within GallSto	66.7%	33.3%	100.0%
		% within Prod	6.7%	3.3%	5.0%
Total		Count	30	30	60
		% within GallSto	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Liver1 * Prod Crosstabulation

			Prod		Total
			0	1	
Liver1	0	Count	30	30	60
		% within Liver1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within Liver1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Bowel1 * Prod Crosstabulation

			Prod		Total
			0	1	
Bowel1	0	Count	30	30	60
		% within Bowel1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within Bowel1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Ulcer1 * Prod Crosstabulation

			Prod		Total
			0	1	
Ulcer1	0	Count	30	30	60
		% within Ulcer1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within Ulcer1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Cancer1 * Prod Crosstabulation

			Prod		Total
			0	1	
Cancer1	0	Count	26	30	56
		% within Cancer1	46.4%	53.6%	100.0%
		% within Prod	86.7%	100.0%	93.3%
	1	Count	4	0	4
		% within Cancer1	100.0%	.0%	100.0%
		% within Prod	13.3%	.0%	6.7%
Total		Count	30	30	60
		% within Cancer1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

HChol1 * Prod Crosstabulation

			Prod		Total
			0	1	
HChol1	0	Count	29	29	58
		% within HChol1	50.0%	50.0%	100.0%
		% within Prod	96.7%	96.7%	96.7%
	1	Count	1	1	2
		% within HChol1	50.0%	50.0%	100.0%
		% within Prod	3.3%	3.3%	3.3%
Total		Count	30	30	60
		% within HChol1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

OsteoA1 * Prod Crosstabulation

			Prod 0	Prod 1	Total
OsteoA1	0	Count	29	30	59
		% within OsteoA1	49.2%	50.8%	100.0%
		% within Prod	96.7%	100.0%	98.3%
	1	Count	1	0	1
		% within OsteoA1	100.0%	.0%	100.0%
		% within Prod	3.3%	.0%	1.7%
Total		Count	30	30	60
		% within OsteoA1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Rhuem1 * Prod Crosstabulation

			Prod 0	Prod 1	Total
Rhuem1	0	Count	30	30	60
		% within Rhuem1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within Rhuem1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

EPI * Prod Crosstabulation

			Prod 0	Prod 1	Total
EPI	0	Count	30	30	60
		% within EPI	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within EPI	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

convul * Prod Crosstabulation

			Prod 0	Prod 1	Total
convul	0	Count	30	30	60
		% within convul	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within convul	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

hemo * Prod Crosstabulation

			Prod		Total
			0	1	
hemo	0	Count	30	30	60
		% within hemo	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within hemo	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

gout * Prod Crosstabulation

			Prod		Total
			0	1	
gout	0	Count	30	30	60
		% within gout	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%
Total		Count	30	30	60
		% within gout	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

migrain * Prod Crosstabulation

			Prod		Total
			0	1	
migrain	0	Count	28	27	55
		% within migrain	50.9%	49.1%	100.0%
		% within Prod	93.3%	90.0%	91.7%
	1	Count	2	3	5
		% within migrain	40.0%	60.0%	100.0%
		% within Prod	6.7%	10.0%	8.3%
Total		Count	30	30	60
		% within migrain	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

dietrest * Prod Crosstabulation

			Prod		Total
			0	1	
dietrest	0	Count	29	30	59
		% within dietrest	49.2%	50.8%	100.0%
		% within Prod	96.7%	100.0%	98.3%
	1	Count	1	0	1
		% within dietrest	100.0%	.0%	100.0%
		% within Prod	3.3%	.0%	1.7%
Total		Count	30	30	60
		% within dietrest	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

other1 * Prod Crosstabulation

			Prod		Total
			0	1	
other1	0	Count	30	29	59
		% within other1	50.8%	49.2%	100.0%
		% within Prod	100.0%	96.7%	98.3%
	1	Count	0	1	1
		% within other1	.0%	100.0%	100.0%
		% within Prod	.0%	3.3%	1.7%
Total		Count	30	30	60
		% within other1	50.0%	50.0%	100.0%
		% within Prod	100.0%	100.0%	100.0%

exercise * Prod Crosstabulation

			Prod		Total
			0	1	
exercise	1	Count	2	5	7
		% within exercise	28.6%	71.4%	100.0%
		% within Prod	7.1%	16.7%	12.1%
	2	Count	10	8	18
		% within exercise	55.6%	44.4%	100.0%
		% within Prod	35.7%	26.7%	31.0%
	3	Count	15	12	27
		% within exercise	55.6%	44.4%	100.0%
		% within Prod	53.6%	40.0%	46.6%
	4	Count	1	4	5
		% within exercise	20.0%	80.0%	100.0%
		% within Prod	3.6%	13.3%	8.6%
	5	Count	0	1	1
		% within exercise	.0%	100.0%	100.0%
		% within Prod	.0%	3.3%	1.7%
Total		Count	28	30	58
		% within exercise	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

health * Prod Crosstabulation

			Prod		Total
			0	1	
health	1	Count	1	1	2
		% within health	50.0%	50.0%	100.0%
		% within Prod	3.6%	3.3%	3.4%
	2	Count	17	11	28
		% within health	60.7%	39.3%	100.0%
		% within Prod	60.7%	36.7%	48.3%
	3	Count	9	15	24
		% within health	37.5%	62.5%	100.0%
		% within Prod	32.1%	50.0%	41.4%
	4	Count	1	3	4
		% within health	25.0%	75.0%	100.0%
		% within Prod	3.6%	10.0%	6.9%
Total		Count	28	30	58
		% within health	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

vitamin * Prod Crosstabulation

			Prod 0	Prod 1	Total
vitamin	0	Count	12	17	29
		% within vitamin	41.4%	58.6%	100.0%
		% within Prod	42.9%	56.7%	50.0%
	1	Count	12	5	17
		% within vitamin	70.6%	29.4%	100.0%
		% within Prod	42.9%	16.7%	29.3%
	2	Count	4	8	12
		% within vitamin	33.3%	66.7%	100.0%
		% within Prod	14.3%	26.7%	20.7%
Total		Count	28	30	58
		% within vitamin	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

altern * Prod Crosstabulation

			Prod 0	Prod 1	Total
altern	0	Count	26	27	53
		% within altern	49.1%	50.9%	100.0%
		% within Prod	92.9%	90.0%	91.4%
	1	Count	1	0	1
		% within altern	100.0%	.0%	100.0%
		% within Prod	3.6%	.0%	1.7%
	2	Count	1	3	4
		% within altern	25.0%	75.0%	100.0%
		% within Prod	3.6%	10.0%	6.9%
Total		Count	28	30	58
		% within altern	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Job * Prod Crosstabulation

			Prod 0	Prod 1	Total
Job	1	Count	1	1	2
		% within Job	50.0%	50.0%	100.0%
		% within Prod	3.6%	3.3%	3.4%
	2	Count	0	1	1
		% within Job	.0%	100.0%	100.0%
		% within Prod	.0%	3.3%	1.7%
	3	Count	1	2	3
		% within Job	33.3%	66.7%	100.0%
		% within Prod	3.6%	6.7%	5.2%
	4	Count	1	0	1
		% within Job	100.0%	.0%	100.0%
		% within Prod	3.6%	.0%	1.7%
	6	Count	8	9	17
		% within Job	47.1%	52.9%	100.0%
		% within Prod	28.6%	30.0%	29.3%
	8	Count	1	2	3
		% within Job	33.3%	66.7%	100.0%
		% within Prod	3.6%	6.7%	5.2%
	9	Count	1	6	7
		% within Job	14.3%	85.7%	100.0%
		% within Prod	3.6%	20.0%	12.1%
	10	Count	7	4	11
		% within Job	63.6%	36.4%	100.0%
		% within Prod	25.0%	13.3%	19.0%
	11	Count	2	0	2
		% within Job	100.0%	.0%	100.0%
		% within Prod	7.1%	.0%	3.4%
	12	Count	6	5	11
		% within Job	54.5%	45.5%	100.0%
		% within Prod	21.4%	16.7%	19.0%
Total		Count	28	30	58
		% within Job	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Hours * Prod Crosstabulation

			Prod 0	Prod 1	Total
Hours	1	Count	19	17	36
		% within Hours	52.8%	47.2%	100.0%
		% within Prod	67.9%	56.7%	62.1%
	2	Count	8	11	19
		% within Hours	42.1%	57.9%	100.0%
		% within Prod	28.6%	36.7%	32.8%
	3	Count	1	2	3
		% within Hours	33.3%	66.7%	100.0%
		% within Prod	3.6%	6.7%	5.2%
Total		Count	28	30	58
		% within Hours	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Income * Prod Crosstabulation

			Prod	Prod	Total
			0	1	
Income	1	Count	6	11	17
		% within income	35.3%	64.7%	100.0%
		% within Prod	21.4%	36.7%	29.3%
	2	Count	8	10	18
		% within income	44.4%	55.6%	100.0%
		% within Prod	28.6%	33.3%	31.0%
	3	Count	8	7	15
		% within income	53.3%	46.7%	100.0%
		% within Prod	28.6%	23.3%	25.9%
	4	Count	4	1	5
		% within income	80.0%	20.0%	100.0%
		% within Prod	14.3%	3.3%	8.6%
	5	Count	2	1	3
		% within income	66.7%	33.3%	100.0%
		% within Prod	7.1%	3.3%	5.2%
Total		Count	28	30	58
		% within income	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Adults * Prod Crosstabulation

			Prod	Prod	Total
			0	1	
Adults	1	Count	6	6	12
		% within Adults	50.0%	50.0%	100.0%
		% within Prod	22.2%	20.7%	21.4%
	2	Count	15	14	29
		% within Adults	51.7%	48.3%	100.0%
		% within Prod	55.6%	48.3%	51.8%
	3	Count	4	7	11
		% within Adults	36.4%	63.6%	100.0%
		% within Prod	14.8%	24.1%	19.6%
	4	Count	0	2	2
		% within Adults	.0%	100.0%	100.0%
		% within Prod	.0%	6.9%	3.6%
	5	Count	2	0	2
		% within Adults	100.0%	.0%	100.0%
		% within Prod	7.4%	.0%	3.6%
Total		Count	27	29	56
		% within Adults	48.2%	51.8%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Kids * Prod Crosstabulation

| | | | Prod | | |
			0	1	Total
Kids	1	Count	13	17	30
		% within Kids	43.3%	56.7%	100.0%
		% within Prod	46.4%	56.7%	51.7%
	2	Count	7	7	14
		% within Kids	50.0%	50.0%	100.0%
		% within Prod	25.0%	23.3%	24.1%
	3	Count	5	3	8
		% within Kids	62.5%	37.5%	100.0%
		% within Prod	17.9%	10.0%	13.8%
	4	Count	3	3	6
		% within Kids	50.0%	50.0%	100.0%
		% within Prod	10.7%	10.0%	10.3%
Total		Count	28	30	58
		% within Kids	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

educate * Prod Crosstabulation

| | | | Prod | | |
			0	1	Total
educate	1	Count	0	4	4
		% within educate	.0%	100.0%	100.0%
		% within Prod	.0%	13.3%	6.9%
	2	Count	5	5	10
		% within educate	50.0%	50.0%	100.0%
		% within Prod	17.9%	16.7%	17.2%
	3	Count	22	15	37
		% within educate	59.5%	40.5%	100.0%
		% within Prod	78.6%	50.0%	63.8%
	4	Count	0	5	5
		% within educate	.0%	100.0%	100.0%
		% within Prod	.0%	16.7%	8.6%
	5	Count	1	1	2
		% within educate	50.0%	50.0%	100.0%
		% within Prod	3.6%	3.3%	3.4%
Total		Count	28	30	58
		% within educate	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Smoke * Prod Crosstabulation

			Prod		Total
			0	1	
Smoke	0	Count	18	12	30
		% within Smoke	60.0%	40.0%	100.0%
		% within Prod	64.3%	40.0%	51.7%
	1	Count	3	3	6
		% within Smoke	50.0%	50.0%	100.0%
		% within Prod	10.7%	10.0%	10.3%
	2	Count	5	5	10
		% within Smoke	50.0%	50.0%	100.0%
		% within Prod	17.9%	16.7%	17.2%
	3	Count	1	9	10
		% within Smoke	10.0%	90.0%	100.0%
		% within Prod	3.6%	30.0%	17.2%
	4	Count	1	1	2
		% within Smoke	50.0%	50.0%	100.0%
		% within Prod	3.6%	3.3%	3.4%
Total		Count	28	30	58
		% within Smoke	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

ETOH * Prod Crosstabulation

			Prod		Total
			0	1	
ETOH	0	Count	14	10	24
		% within ETOH	58.3%	41.7%	100.0%
		% within Prod	50.0%	33.3%	41.4%
	1	Count	8	8	16
		% within ETOH	50.0%	50.0%	100.0%
		% within Prod	28.6%	26.7%	27.6%
	2	Count	4	3	7
		% within ETOH	57.1%	42.9%	100.0%
		% within Prod	14.3%	10.0%	12.1%
	3	Count	1	6	7
		% within ETOH	14.3%	85.7%	100.0%
		% within Prod	3.6%	20.0%	12.1%
	4	Count	1	3	4
		% within ETOH	25.0%	75.0%	100.0%
		% within Prod	3.6%	10.0%	6.9%
Total		Count	28	30	58
		% within ETOH	48.3%	51.7%	100.0%
		% within Prod	100.0%	100.0%	100.0%

Depr1 * Prod

Crosstab

Count

		Prod		Total
		0	1	
Depr1	0	28	22	50
	1	2	8	10
Total		30	30	60

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	4.320[b]	1	.038		
Continuity Correction[a]	3.000	1	.083		
Likelihood Ratio	4.577	1	.032		
Fisher's Exact Test				.080	.040
Linear-by-Linear Association	4.248	1	.039		
N of Valid Cases	60				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 5.00.

Surg1 * Prod

Crosstab

Count

		Prod		Total
		0	1	
Surg1	0	20	24	44
	1	10	6	16
Total		30	30	60

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	1.364[b]	1	.243		
Continuity Correction[a]	.767	1	.381		
Likelihood Ratio	1.375	1	.241		
Fisher's Exact Test				.382	.191
Linear-by-Linear Association	1.341	1	.247		
N of Valid Cases	60				

a. Computed only for a 2x2 table

b. 0 cells (.0%) have expected count less than 5. The minimum expected count is 8.00.

again1 * Prod Crosstabulation

Count

		Prod		Total
		0	1	
again1	0	1	1	2
	1	4	13	17
	2	3	6	9
Total		8	20	28

again2 * Prod Crosstabulation

Count

		Prod		Total
		0	1	
again2	0	1	3	4
	1	5	15	20
	2	6	3	9
Total		12	21	33

Crosstabs

recomm1 * Prod Crosstabulation

Count

		Prod		Total
		0	1	
recomm1	0	0	2	2
	1	6	13	19
	2	2	5	7
Total		8	20	28

recomm2 * Prod Crosstabulation

Count

		Prod		Total
		0	1	
recomm2	0	1	4	5
	1	7	15	22
	2	4	2	6
Total		12	21	33

T-Test

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
weight0	0	30	190.140	21.2925	3.8875
	1	30	195.057	31.0174	5.6630

Independent Samples Test

		Levene's Test for Equality of Variances	
		F	Sig.
weight0	Equal variances assumed	5.479	.023
	Equal variances not assumed		

Independent Samples Test

		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
weight0	Equal variances assumed	-.716	58	.477	-4.917
	Equal variances not assumed	-.716	51.365	.477	-4.917

| | | t-test for Equality of Means | | |
| | | | 95% Confidence Interval of the Difference | |
		Std. Error Difference	Lower	Upper
weight0	Equal variances assumed	6.8689	-18.6662	8.8329
	Equal variances not assumed	6.8689	-18.7042	8.8708

T-Test

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
WI_1	0	30	4.3400	1.64161	.29972
	1	30	7.4567	2.41699	.44128

Independent Samples Test

		Levene's Test for Equality of Variances	
		F	Sig.
WI_1	Equal variances assumed	2.475	.121
	Equal variances not assumed		

		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
W1_1	Equal variances assumed	-5.843	58	.000	-3.1167
	Equal variances not assumed	-5.843	51.061	.000	-3.1167

Independent Samples Test

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
WT_1	Equal variances assumed	.53344	-4.18446	-2.04887
	Equal variances not assumed	.53344	-4.18756	-2.04577

Summarize

Case Processing Summary

| | Cases | | | | | |
| | Included | | Excluded | | Total | |
	N	Percent	N	Percent	N	Percent
weight0 * Prod	60	100.0%	0	.0%	60	100.0%
WT_1 * Prod	60	100.0%	0	.0%	60	100.0%
ID * Prod	60	100.0%	0	.0%	60	100.0%

Case Summaries

			weight0	WT_1	ID
Prod	0	1	218.4	-.20	70046
		2	163.0	2.60	70032
		3	189.4	2.60	70004
		4	198.4	2.80	70054
		5	193.4	3.20	70061
		6	190.5	3.30	70047
		7	205.4	3.40	70057
		8	153.4	3.60	70003
		9	202.0	3.60	70052
		10	206.6	3.70	70051
		11	202.7	3.70	70060
		12	183.7	3.80	70067
		13	192.9	3.80	70063
		14	187.0	3.80	70064
		15	188.4	3.90	70062
		16	153.2	4.20	70035
		17	207.8	4.20	70071
		18	178.7	4.50	70025
		19	200.9	4.60	70059
		20	183.4	4.60	70056
		21	156.4	5.00	70042
		22	239.6	5.00	70018
		23	157.8	5.40	70021
		24	192.9	5.40	70070
		25	205.0	5.40	70033
		26	159.8	5.60	70014
		27	194.9	5.70	70069
		28	207.4	6.60	70066
		29	171.2	8.00	70034
		30	220.0	8.40	70036
	Total	N	30	30	30

Case Summaries

			weight0	WT_1	ID
Prod	1	1	164.8	2.00	70026
		2	146.6	2.60	70040
		3	157.0	5.20	70029
		4	174.0	5.20	70027
		5	184.2	5.40	70045
		6	172.3	5.50	70053
		7	164.0	5.60	70049
		8	250.4	5.80	70017
		9	179.8	6.00	70005
		10	169.7	6.50	70068
		11	188.2	6.80	70050
		12	179.6	7.00	70037
		13	257.7	7.10	70008
		14	173.1	7.40	70055
		15	192.0	7.60	70023
		16	228.4	7.60	70024
		17	203.8	7.60	70031
		18	236.8	7.60	70009
		19	172.6	8.00	70022
		20	168.2	8.10	70012
		21	230.8	8.20	70006
		22	209.9	8.50	70010
		23	207.6	8.60	70001
		24	170.3	8.60	70058
		25	179.6	9.30	70030
		26	207.4	9.40	70007
		27	192.3	10.10	70065
		28	250.6	10.80	70019
		29	246.0	12.40	70020
		30	194.0	13.20	70002
	Total	N	30	30	30
Total	N		60	60	60

Case Summaries

			weight0	WT_1	ID
Prod 1		1	146.6	2.60	70040
		2	157.0	5.20	70029
		3	164.0	5.60	70049
		4	164.8	2.00	70026
		5	168.2	8.10	70012
		6	169.7	6.50	70068
		7	170.3	8.60	70058
		8	172.3	5.50	70053
		9	172.6	8.00	70022
		10	173.1	7.40	70055
		11	174.0	5.20	70027
		12	179.6	7.00	70037
		13	179.6	9.30	70030
		14	179.8	6.00	70005
		15	184.2	5.40	70045
		16	188.2	6.80	70050
		17	192.0	7.60	70023
		18	192.3	10.10	70065
		19	194.0	13.20	70002
		20	203.8	7.60	70031
		21	207.4	9.40	70007
		22	207.6	8.60	70001
		23	209.9	8.50	70010
		24	228.4	7.60	70024
		25	230.8	8.20	70006
		26	236.8	7.60	70009
		27	246.0	12.40	70020
		28	250.4	5.80	70017
		29	250.6	10.80	70019
		30	257.7	7.10	70008
	Total	N	30	30	30
Total	N		60	60	60

Case Summaries

			weight0	WT_1	ID
Prod	0	1	153.2	4.20	70035
		2	153.4	3.60	70003
		3	156.4	5.00	70042
		4	157.8	5.40	70021
		5	159.8	5.60	70014
		6	163.0	2.60	70032
		7	171.2	8.00	70034
		8	178.7	4.50	70025
		9	183.4	4.60	70056
		10	183.7	3.80	70067
		11	187.0	3.80	70064
		12	188.4	3.90	70062
		13	189.4	2.60	70004
		14	190.5	3.30	70047
		15	192.9	3.80	70063
		16	192.9	5.40	70070
		17	193.4	3.20	70061
		18	194.9	5.70	70069
		19	198.4	2.80	70054
		20	200.9	4.60	70059
		21	202.0	3.60	70052
		22	202.7	3.70	70060
		23	205.0	5.40	70033
		24	205.4	3.40	70057
		25	206.6	3.70	70051
		26	207.4	6.60	70066
		27	207.8	4.20	70071
		28	218.4	-.20	70046
		29	220.0	8.40	70036
		30	239.6	5.00	70018
	Total	N	30	30	30

Crosstabs

RISK * Prod Crosstabulation

Count

		Prod		Total
		0	1	
RISK	.00	14	15	29
	1.00	7	8	15
	2.00	6	4	10
	3.00	2	2	4
	4.00	0	1	1
	6.00	1	0	1
Total		30	30	60

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
RISK	0	30	1.0333	1.35146	.24674
	1	30	.8667	1.10589	.20191

Independent Samples Test

		Levene's Test for Equality of Variances	
		F	Sig.
RISK	Equal variances assumed	.301	.585
	Equal variances not assumed		

Independent Samples Test

		t-test for Equality of Means			
		t	df	Sig. (2-tailed)	Mean Difference
RISK	Equal variances assumed	.523	58	.603	.1667
	Equal variances not assumed	.523	55.814	.603	.1667

		t-test for Equality of Means		
		Std. Error Difference	95% Confidence Interval of the Difference	
			Lower	Upper
RISK	Equal variances assumed	.31882	-.47153	.80486
	Equal variances not assumed	.31882	-.47206	.80539

Group Statistics

	Prod	N	Mean	Std. Deviation	Std. Error Mean
REAL_IN1	0	27	1.3519	.69849	.13442
	1	29	1.1293	.73987	.13739
REAL_IN2	0	27	.6690	.31565	.06075
	1	29	.5984	.36320	.06745

HOLLYWOOD
48 HOUR MIRACLE DIET

Prospective, Randomized, Double-Blind Placebo-Controlled, Clinical Trial

Sunset Health Products, Inc.
Los Angeles, CA

Results:
June 9, 2003

06/09/03
MarshallBlum

HOLLYWOOD
48 HOUR MIRACLE DIET

	Placebo	Product
Start	32	32
Complete	30	30

06/09/03
MarshallBlum

Mean Weight Loss (60 Hours)
Mean Difference From Baseline

Weight Loss Distribution (60 Hours)
Mean Difference From Baseline

"How Do You Feel Now?" (Day 7)

"How is you Energy Level Now?" (Day 7)

6

"Would you use this product again?"

"Would you recommend this product to a friend?"
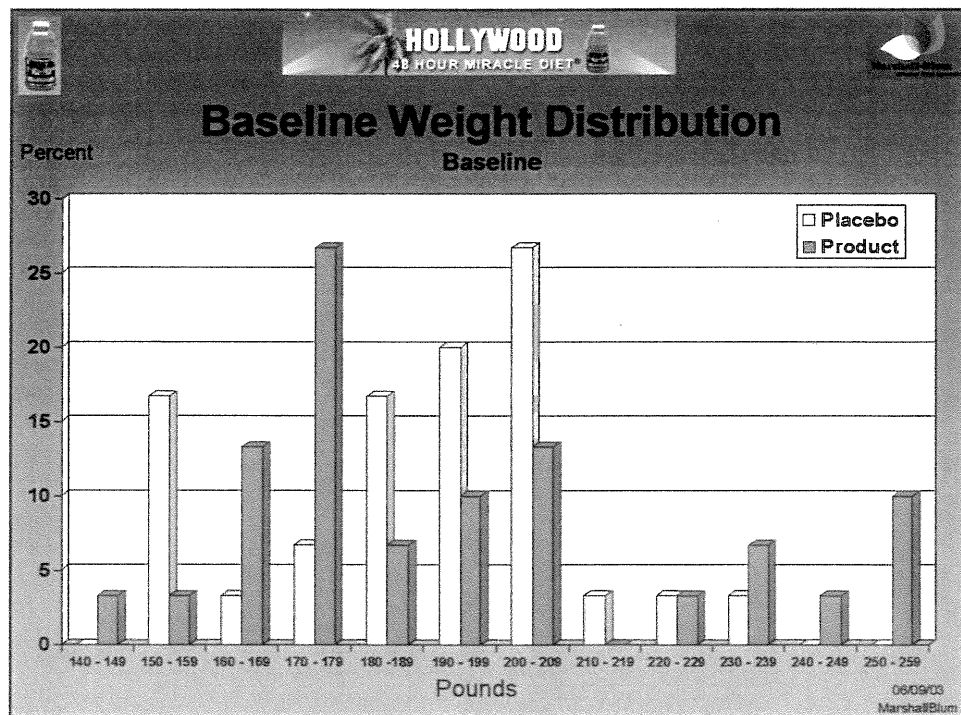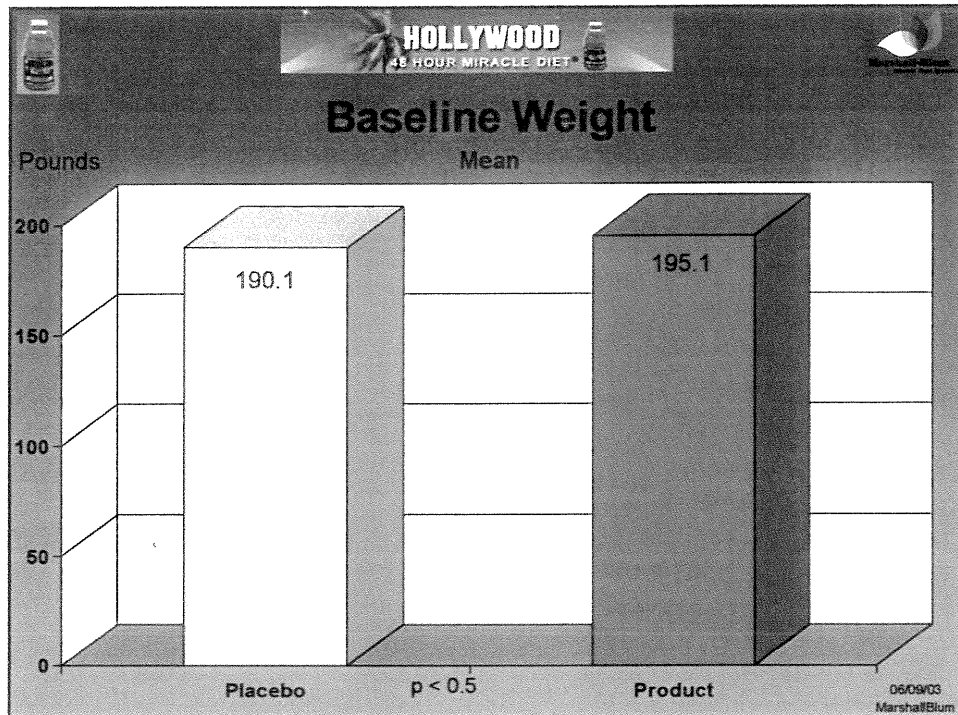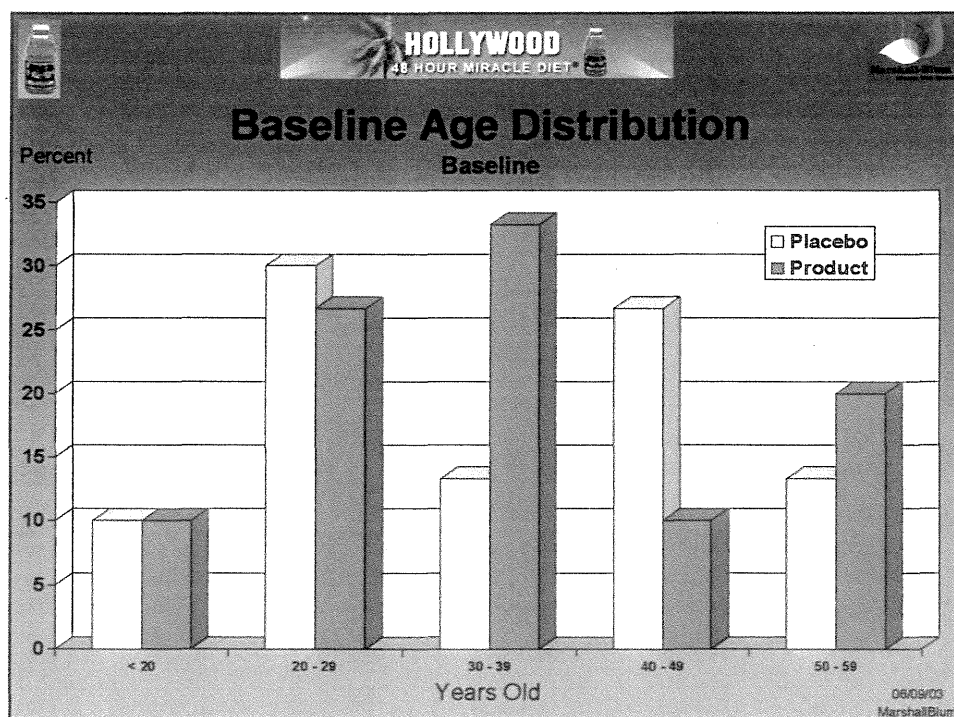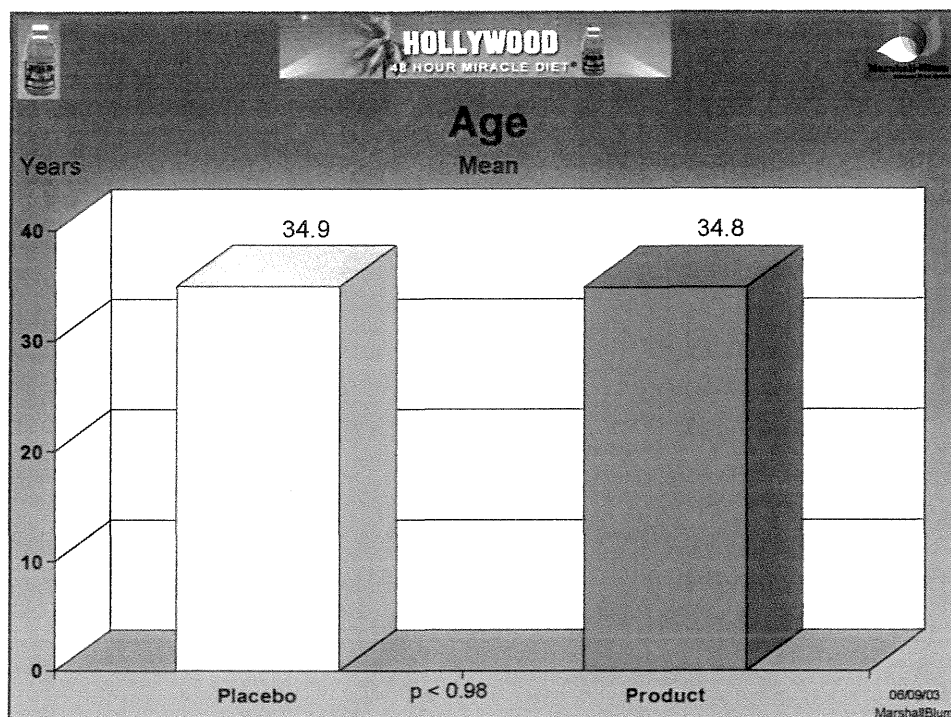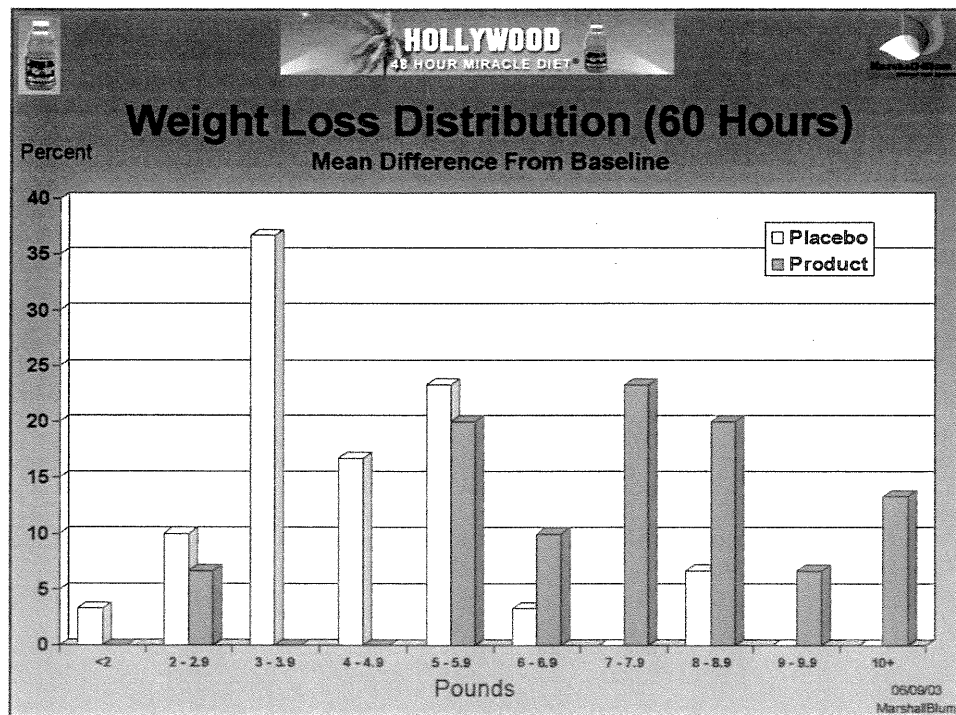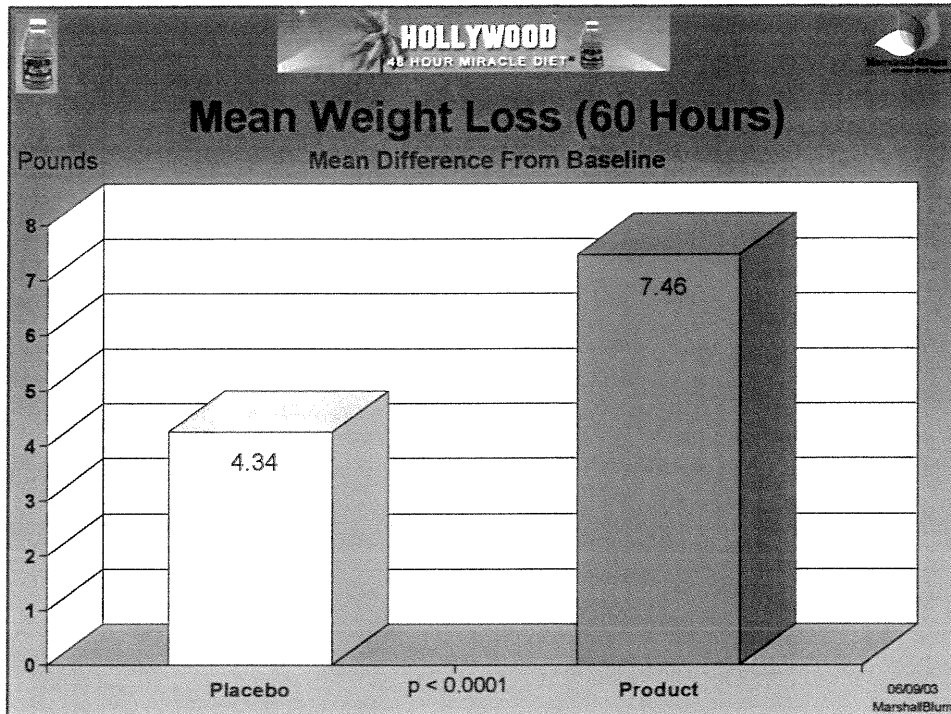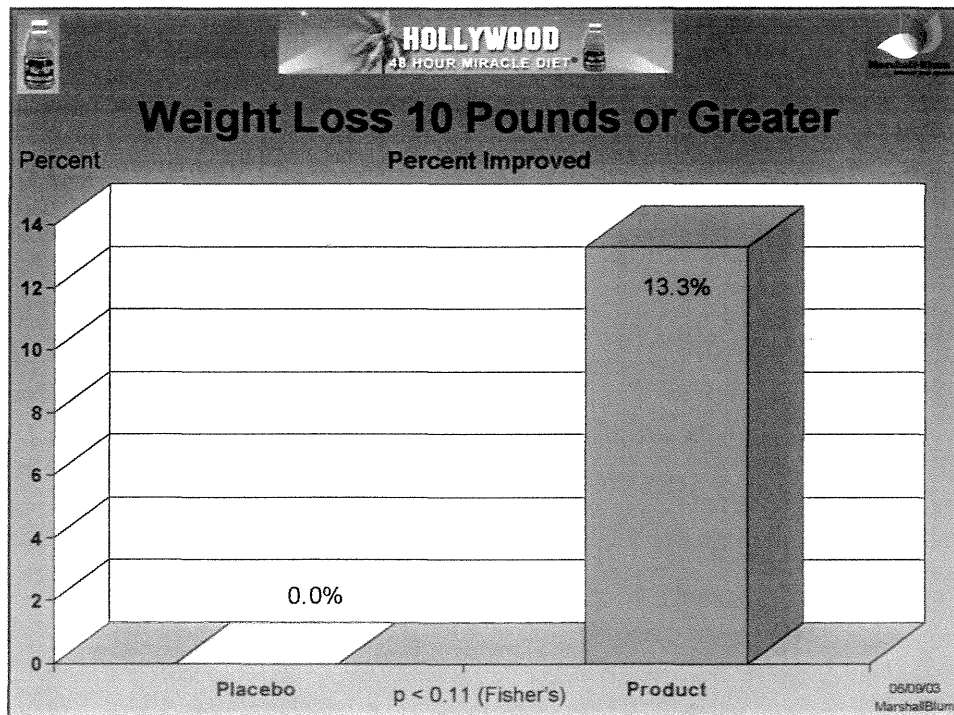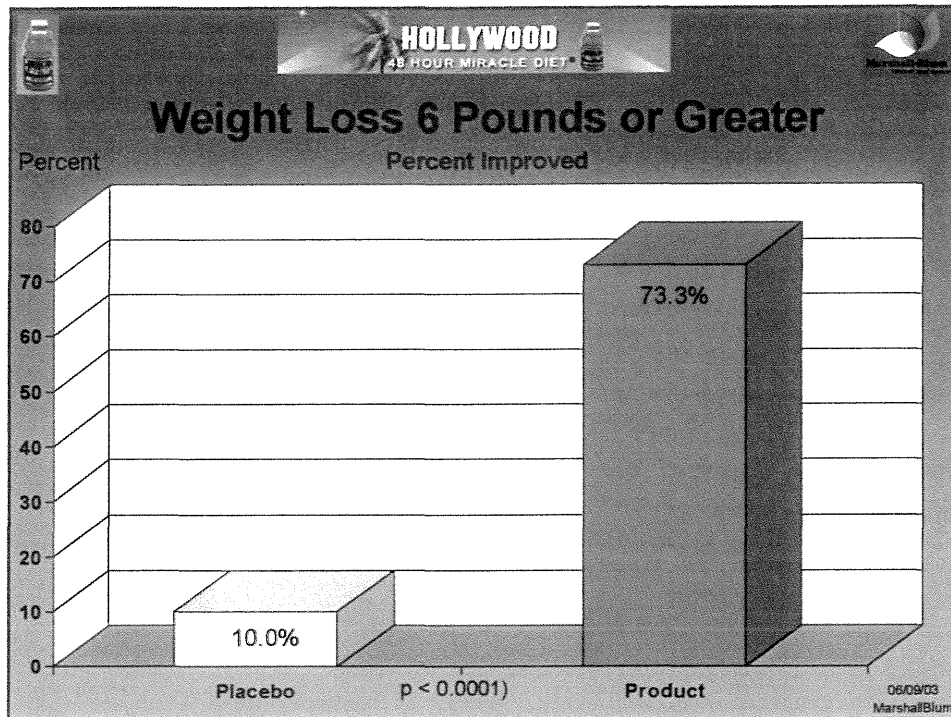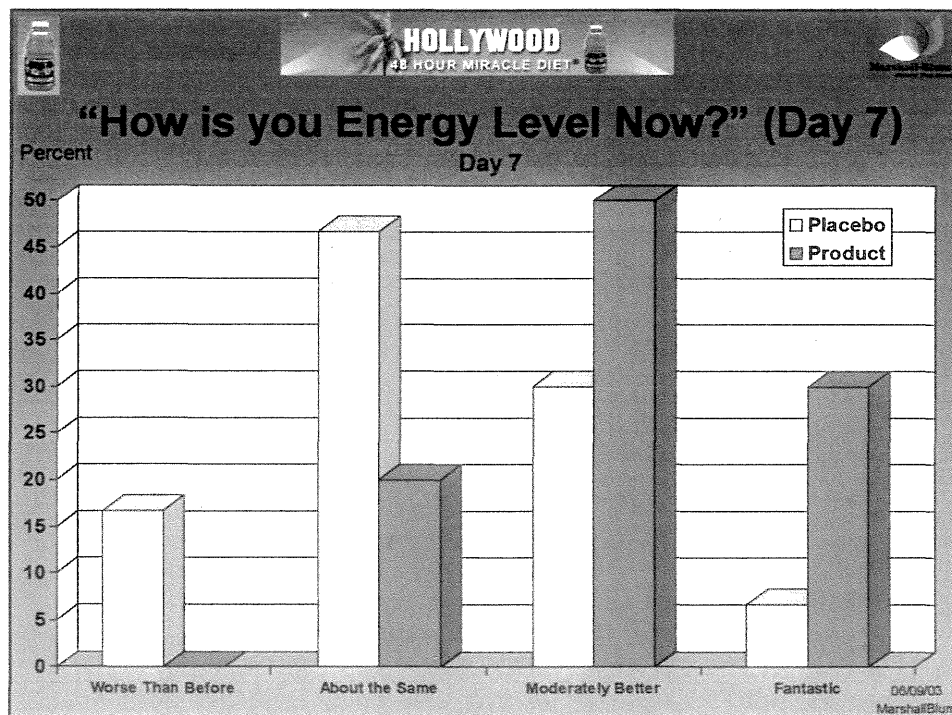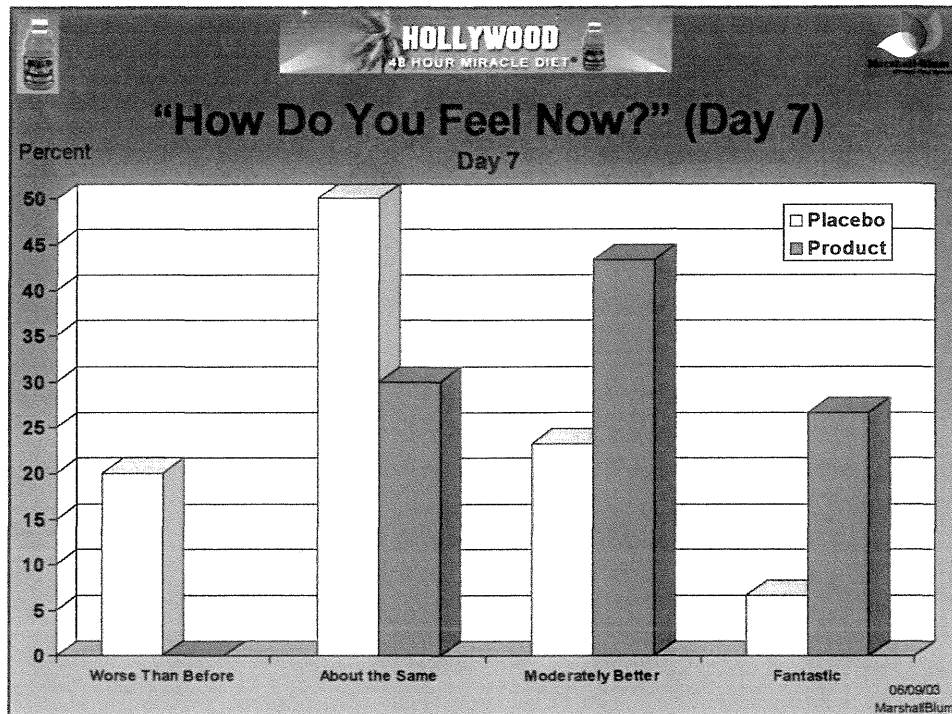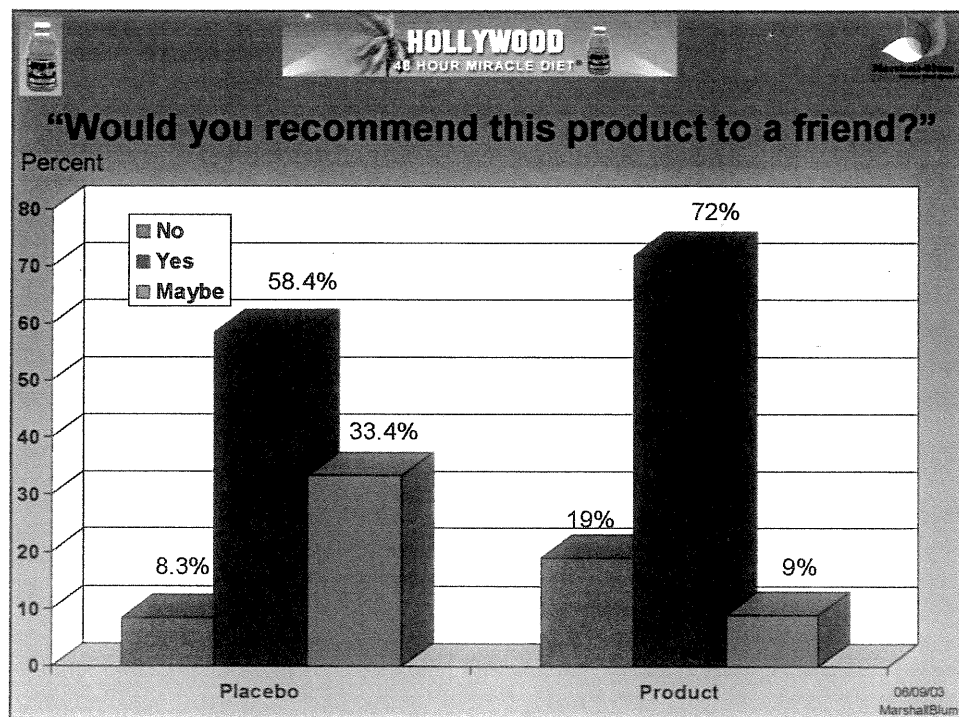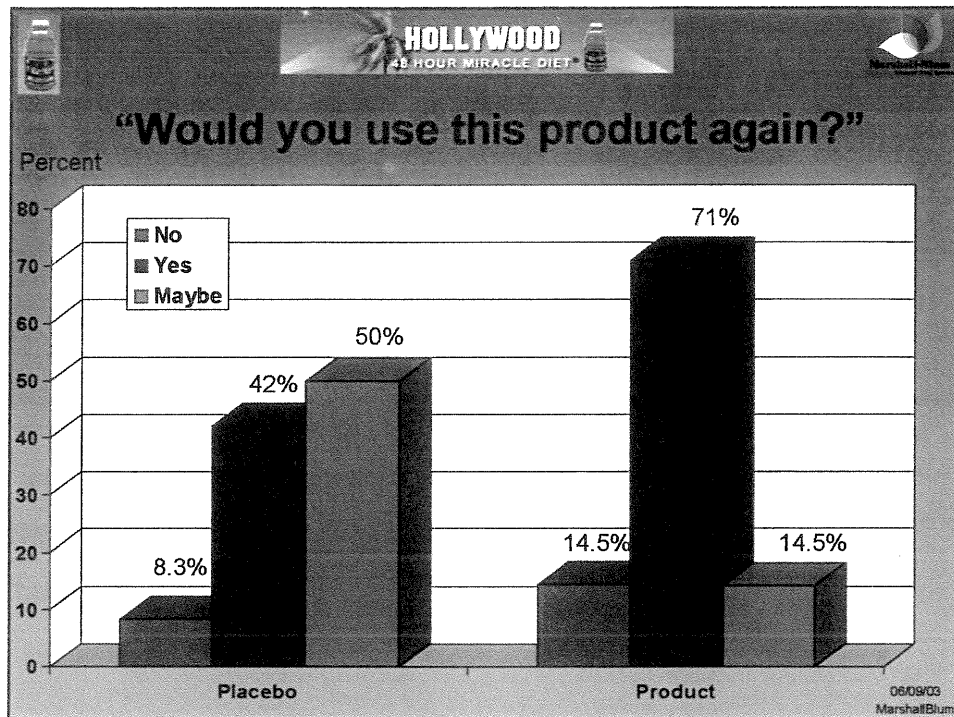
Client: Sunset Health Products, Inc.
Demographics and Baseline Profile (1 of 5)

All Data is a % unless indicated	Control	Product
Risk Factors		
Age: Mean	34.9	34.8
Weight: Mean	190.1	195.1
Body Mass Index: Mean	33.5	32.1
Gender: Female	90.0	83.3
Asthma	13.3	6.7
Cancer	13.3	0.0
Cardiac	0.0	0.0
Convulsion	0.0	0.0
COPD[1]	0.0	0.0
Diabetes	0.0	0.0
Depression	6.7	26.7 ($p < 0.04$)
Epilepsy	0.0	0.0
Gall Attack	3.3	3.3
Gall Stones	6.7	3.3
Gastrointestinal Conditions	0.0	0.0
Gout	0.0	0.0
Hemophilia	0.0	0.0
High Cholesterol	3.3	3.3
Hypertension	6.7	3.3
Injury (Miscellaneous)	13.3	13.3
Liver Insuffiency	0.0	0.0
Migraine	6.7	10.0
Osteoarthritis	3.3	0.0
Other Medications	0.0	3.3
Renal Insuffiency	0.0	0.0
Rhuematoid Arthritis	0.0	0.0
Surgery, Previous	33.3	20 ($p < 0.2$)
Thyroid Disease	3.3	3.3

[1] = Chronic Obstructive Pulmonary Disease

Marshall-Blum LLC

Client: Sunset Health Products, Inc.
Demographics and Baseline Profile (2 of 5)

All Data is a % unless indicated	Control	Product
Behavioral		
Caffeine (3 or > Cups / Day)	20.0	26.7
Caffeine (Mean Cups / Day)	1.6	1.8
Alcohol > 3 Drinks / Week	3.6	10.0
Smoking		
Never	64.3	40.0
No, Quit < 2 years	10.7	10.0
No, Quit > 2 years	17.9	16.7
Yes, < 1 Pack / Day	3.6	30.0
Yes, > 1 Pack / Day	3.6	3.3
Risk		
High Risk Category[2]	10.0	10.0
Mean Risk Score	1.03	0.87 (p < 0.6)

[2] = 3 or more points of above parameters

Marshall-Blum LLC

All Data is a % unless indicated	Control	Product
Demographics		
Job		
Clerical	3.6	3.3
Homemaker	3.6	6.7
Management	3.6	0.0
Professional	28.6	30.0
Retired / Self Employed	3.6	6.7
Teaching / Student	32.1	13.3
Other	25.0	40.0
* Other includes Craft/Technical, Military, Service Ind. and Not Working		
Hours Worked Per Week		
36 or More	67.9	56.7
Less Than 36	32.2	43.4
Income		
Under $20k	21.4	36.7
$20k and under $40k	28.6	33.3
$40k and under $60k	28.6	23.3
$60k and under $80k	14.3	3.3
$80k and under $100k	7.1	3.3
$100k and Above	0.0	0.0
Adults in Household		
1	22.2	20.7
2	55.6	48.3
3	14.8	24.1
4 or More	7.4	6.9
Children in Household		
0	46.4	56.7
1	25.0	23.3
2	17.9	10.0
3	10.7	10.0
4 or More	0.0	0.0

Marshall-Blum LLC

Client: Sunset Health Products, Inc.
Demographics and Baseline Profile (4 of 5)

All Data is a % unless indicated	Control	Product
Real Income[3]: Adults		
< 0.5	3.7	13.8
0.5 - <1.0	18.5	24.1
1.0 - <1.5	29.6	27.6
1.5 - <2.0	22.2	17.2
2.0 or >	25.9	17.2
Mean	1.35	1.12
Real Income[4]: Adults & Kids		
< 0.5	25.9	41.4
0.5 - <1.0	51.9	31.0
1.0 - <1.5	18.5	24.1
1.5 - <2.0	3.7	3.4
2.0 or >	0.0	0.0
Mean	0.67	0.60
Education		
Less Than High School	0.0	13.3
High School	17.9	16.7
Vocational / A.S. Degree	78.6	50.0
B.S. Degree	0.0	16.7
Graduate Degree	3.6	3.3
Doctorate or Professional	0.0	0.0
Exercise: Times / Week		
1	7.1	16.7
2	35.7	26.7
3	53.6	40.0
4	3.6	13.3
5 or More	0.0	3.3

Marshall-Blum LLC

Client: Sunset Health Products, Inc.
Demographics and Baseline Profile (5 of 5)

All Data is a % unless indicated	Control	Product
Health: Self Assessment		
Excellent	3.6	3.3
Very Good	60.7	36.7
Good	32.1	50.0
Fair	3.6	10.0
Poor	0.0	0.0
Use Vitamins		
Yes	42.9	16.7
Sometimes	14.3	26.7
No	42.9	56.7
Use Herbal Supplements		
Yes	21.4	6.7
Sometimes	10.7	23.3
No	67.9	70.0
Use Non-Physician Healthcare		
Yes	3.6	0.0
Sometimes	3.6	10.0
No	92.9	90.0

Marshall-Blum LLC

Diet (SUNSET) Intake Form
Marshall-Blum LLC

Date: ___/___/___   ID#: _____

ALL SUBJECTS:

Initial Visit: **SUNSET1**   ___/___/___   Time: _____

1-Day Visit: **SUNSET2**   ___/___/___   Time: _____ (approx. 6pm to 7pm)

4-Day Visit: **SUNSET3**   ___/___/___   Time: _____ (approx. 7am to 8am)

7-Day Visit: **SUNSET4**   ___/___/___   Time: _____

Signed Photo Release: 0. ☐ No   1. ☐ Yes

Compensation: $____.00 paid ___/___/___ check # _____.   Initials _____

_____ bottle(s) of free product dispensed.   Initials _____

END OF STUDY – NO FURTHER DATA REQUIRED – NO CROSSOVER

First Name: _____ Middle Initial: _____ Last Name: _____

Mailing Address: _____

City: _____ State: _____ Zip Code: _____

Phone: (____) ____-_____   Phone: (____) ____-_____

Is it okay to leave a message?   0. ☐ No   1. ☐ Yes

Email: _____ Age: _____ (18-55)

Height: ___'___"   Weight: _____ lbs.   Estimated BMI: _____ (33-40)

BMI qualification (see Body Mass Index Qualifying Chart):   0. ☐ No (exclusionary)   1. ☐ Yes

Are you insulin dependent diabetic: 0. ☐ No   1. ☐ Yes (exclusionary)

Do you have uncontrolled high blood pressure: 0. ☐ No   1. ☐ Yes (exclusionary)

Are you nursing, pregnant, or trying to become pregnant: 0. ☐ No   1. ☐ Yes (exclusionary)

Do you have chronic diarrhea or loose stools: 0. ☐ No   1. ☐ Yes (exclusionary)

Do you have chronic abdominal pain: 0. ☐ No   1. ☐ Yes (exclusionary)

Continued on back

Have you taken any medications or dietary supplements
for weight loss within the past 30 days:　　　　0. ⊔ No　　　1. ⊔ Yes (wait period)

Do you have any major medical conditions:　　　　0. ⊔ No　　　1. ⊔ Yes (nurse review)
(H/O stroke, cancer, kidney disease, liver disease)

Usual Caffeine Intake _____ (cups/day)
Are you willing to restrict caffeine intake for this trial:　　0. ⊔ No (exclusionary)　1. ⊔ Yes
　　　　　　　　　　　　　　　　　　　　　　　　　　2. ⊔ N/A

Usual Alcohol Intake _____ (≤6 drinks/week)
Are you willing to stop all alcohol intake for this trial:　　0. ⊔ No (exclusionary)　1. ⊔ Yes
　　　　　　　　　　　　　　　　　　　　　　　　　　2. ⊔ N/A

Usual Nicotine Use _____ (packs/day of cigarettes or equivalent)
Are you willing to stop all nicotine use for this trial:　　0. ⊔ No (exclusionary)　1. ⊔ Yes
　　　　　　　　　　　　　　　　　　　　　　　　　　2. ⊔ N/A

Current Medications: _____

_____

Exclusionary Meds: warfarin (coumadin), heparin, levodopa, >2 aspirin per day or any other blood thinning
medications, calcium channel-blockers, dilantin, digoxin or other prescribed cardiac glycosides, MAO Inhibitors.
Nurse will evaluate others.

Health Concerns/Comments: _____

_____

How did you hear about this clinical trial: _____
Trial length: 7 days (2 days on assigned product). **Clinic Visits:** Initial, 1-day, 4-day and 7-day. **Ingredients:**
Purified water, pineapple juice concentration, apple juice concentration, orange juice concentration, apricot puree,
peach puree, banana puree, vitamin A, beta carotene, vitamin C, calcium, iron, sodium, thiamine (B1), riboflavin
(B2), niacin (B3), pantothenic acid (B5), pyridoxine (B6), folic acid (B9), cobalamin (B12), vitamin D and vitamin
E. **Randomization:** 1:1. 50% chance of being on active product. **Some possible side effects:** Abdominal
cramping, anemia, bright yellow urine, constipation, diarrhea, dry mouth, false-positive for diabetes, fatigue,
flushing, headache, increased urination, loss of appetite, metallic taste, nausea, stomach pain, thirst, vomiting and
weakness.

Special Instructions:
1. Time Commitment
- Initial visit　　SUNSET1　　45 minutes
- 1-Day visit　　SUNSET2　　30 minutes at night after their evening meal (6pm to 7pm)
- 4-Day visit　　SUNSET3　　30 minutes in the morning before eating or drinking
　　　　　　　　　　　　　　　　　　　　(7am to 8am)
- 7-Day visit　　SUNSET4　　30 minutes
2. Compensation
- All subjects who complete all of the study visits and requirements will receive 1 free bottle of the
active product and $50.00 in compensation.

END

Demographic Form
Marshall-Blum, LLC

Study: _____

Date: ____/____/____   ID#: _____

This survey asks you general demographic questions. It is intended to give us a snapshot of the population that is in this study. All information is strictly confidential and is presented in a cumulative summarized form. We greatly appreciate your help and cooperation in this matter.

Please answer every question by marking one box. If you are unsure about an answer, please give the best answer you can. If you feel uncomfortable answering a question, please skip that question and move to the next one.

1. Please select the appropriate gender category: 1. ❑ Male   2. ❑ Female

2. Your current age is: _____ years

3. Please select your ethnic origin:

1. ❑ Asian or Pacific Islander   4. ❑ Native American or Alaskan Native
2. ❑ Black   5. ❑ White
3. ❑ Hispanic   6. ❑ Other, please specify: _____

4. Your current weight is approximately: _____ pounds

5. Your height is approximately: (feet and inches): _____ft / _____inches

6. Please indicate the category that best describes your current occupation/homemaking status:

1. ❑ clerical   2. ❑ craftsperson/technical   3. ❑ homemaker   4. ❑ management
5. ❑ military   6. ❑ professional   7. ❑ retired   8. ❑ self-employed
9. ❑ service industry 10. ❑ student   11. ❑ teaching   12. ❑ not working
12. ❑ Details or Other, please specify: _____

7. In the above mentioned jobs / duties, do you work:

1. ❑ 36 hours or More
2. ❑ Less than 36 hours
3. ❑ Not Applicable

8. Please indicate the category that best represents your total annual household income (all sources), before taxes:

1. ❑ Under $20,000   4. ❑ $60,000 and under $80,0000
2. ❑ $20,000 and under $40,000   5. ❑ $80,000 and under $100,000
3. ❑ $40,000 and under $60,000   6. ❑ $100,000 and above

Continued on back

9. Including yourself, how many adults live in your household (18 years old or Over)?
1. ❑ 1   2. ❑ 2   3. ❑ 3   4. ❑ 4   5. ❑ 5-6   6. ❑ 7 or more

10. How many people under 18 years old live in your household?
1. ❑ 0   2. ❑ 1   3. ❑ 2   4. ❑ 3   5. ❑ 4   6. ❑ 5 or more

11. Please indicate the highest level of education that you have achieved?
1. ❑ Did not graduate from High School
2. ❑ Graduated High School
3. ❑ Some college or vocational training or Associate Degree
4. ❑ Bachelor Degree and/or Some-Post-Graduate
5. ❑ Graduate Degree
6. ❑ Doctorate or Professional Degree

12. Please indicate your current smoking status?
0. ❑ I have never smoked   ╱
1. ❑ No, I quit in the last two years
2. ❑ No, I quit more than two years ago
3. ❑ Yes, I smoke less than 1 pack a day
4. ❑ Yes, I smoke one pack or more a day

13. If an alcoholic drink is defined as: one bottle/can of beer <u>equals</u> one glass of wine <u>equals</u> one ounce of hard liquor, *how may drinks do you consume in an average week:*
0. ❑ None   1. ❑ average less than 1   2. ❑ 1- 2   3. ❑ 3-4   4. ❑ 5-6   5. ❑ 7-8
6. ❑ 9-10   7. ❑ more than 10

14. How many times each week do you exercise?
1. ❑ Less than 1   2. ❑ 1-2   3. ❑ 3-4   4. ❑ 5-6
5. ❑ 7-8   6. ❑ 9 or more

15. In general, would you say your health is:
1. ❑ Excellent   2. ❑ Very Good   3. ❑ Good   4. ❑ Fair   5. ❑ Poor

16. Do you use vitamin supplements?
1. ❑ Yes   0. ❑ No   2. ❑ Sometimes

17. Do you use herbal supplements?
1. ❑ Yes   0. ❑ No   2. ❑ Sometimes

18. Do you use any non-physician practitioners for your medical care?
1. ❑ Yes   0. ❑ No   2. ❑ Sometimes

END – Thank you for your participation

Diet (SUNSET) Initial Visit Form
Marshall-Blum LLC

Date: ___/___/___   ID#:_____

Visit: <u>Baseline</u>

			Condition	Description
Your Medical History (please mark a box for each condition and describe if you mark "Yes"):				
1.	0. ❑ No	1. ❑ Yes	Diabetes	_____
2.	0. ❑ No	1. ❑ Yes	High Blood Pressure	_____
3.	0. ❑ No	1. ❑ Yes	Thyroid Disease	_____
4.	0. ❑ No	1. ❑ Yes	Asthma	_____
5.	0. ❑ No	1. ❑ Yes	COPD (Lung Disease)	_____
6.	0. ❑ No	1. ❑ Yes	Heart Disease	_____
7.	0. ❑ No	1. ❑ Yes	Depression	_____
8.	0. ❑ No	1. ❑ Yes	Previous Injuries	_____
9.	0. ❑ No	1. ❑ Yes	Previous or Planned Surgeries	_____
10.	0. ❑ No	1. ❑ Yes	Kidney Disease	_____
11.	0. ❑ No	1. ❑ Yes	Kidney Stones	_____
12.	0. ❑ No	1. ❑ Yes	Gallbladder Attack	_____
13.	0. ❑ No	1. ❑ Yes	Gallstones	_____
14.	0. ❑ No	1. ❑ Yes	Liver Disease	_____
15.	0. ❑ No	1. ❑ Yes	Bowel Disease	_____
16.	0. ❑ No	1. ❑ Yes	Ulcer or Stomach Disease	_____
17.	0. ❑ No	1. ❑ Yes	Any Cancer	

Continued on back

	Condition	Description
18. 0. ☐ No 1. ☐ Yes	High Cholesterol	_____
19. 0. ☐ No 1. ☐ Yes	Osteoarthritis	_____
20. 0. ☐ No 1. ☐ Yes	Rheumatoid Arthritis	_____
21. 0. ☐ No 1. ☐ Yes	Epilepsy	_____
22. 0. ☐ No 1. ☐ Yes	Convulsions	_____
23. 0. ☐ No 1. ☐ Yes	Seizures	_____
24. 0. ☐ No 1. ☐ Yes	Hemophilia (a bleeding disorder)	_____
25. 0. ☐ No 1. ☐ Yes	Gout	_____
26. 0. ☐ No 1. ☐ Yes	Migraines	_____
27. 0. ☐ No 1. ☐ Yes	Any Diet Restrictions	_____
28. 0. ☐ No 1. ☐ Yes	Other	

29. Medicines: _____

_____

30. Dietary Supplements: _____

_____

31. Alternative Therapies: _____

32. Allergies: _____

_____

33. Some testing equipment contains latex. Do you have an allergy to latex?

    0. ☐ No   1. ☐ Yes   2. ☐ Uncertain

Continued on next page

Weight Loss

34. Do you plan your meals? (plan = having a "menu" and buying groceries ahead of time)
    1. ❑ All of the time (100%)
    2. ❑ Nearly all of the time (90%)
    3. ❑ Most of the time (75%)
    4. ❑ Half of the time (50%)
    5. ❑ Some of the time (25%)
    6. ❑ Almost none of the time (10%)
    7. ❑ None of the time (0%)
    8. ❑ Uncertain / Unknown

35. Do you have set times for your meals? (ex. = breakfast 7:30am-8:00am, lunch 11:30am-12:30am, etc.)
    1. ❑ All of the time (100%)
    2. ❑ Nearly all of the time (90%)
    3. ❑ Most of the time (75%)
    4. ❑ Half of the time (50%)
    5. ❑ Some of the time (25%)
    6. ❑ Almost none of the time (10%)
    7. ❑ None of the time (0%)
    8. ❑ Uncertain / Unknown

36. How much weight would you like to lose? _____ pounds

37. How many waist inches would you like to lose? _____ inches

38. Have you ever been advised by a doctor or other healthcare professional to lose weight?
    0. ❑ No
    1. ❑ Yes
    2. ❑ Uncertain / Unknown

39. How many years have you been trying to lose weight?
    1. ❑ Less than 1
    2. ❑ 1
    3. ❑ 2
    4. ❑ 3 to 5
    5. ❑ 5 to 10
    6. ❑ 10 or more
    7. ❑ Uncertain / Unknown

Continued on back

40. How many different weight programs or diets have you tried?
     1. ❏ Less than 1
     2. ❏ 1
     3. ❏ 2
     4. ❏ 3 to 5
     5. ❏ 5 to 10
     6. ❏ 10 or more
     7. ❏ Uncertain / Unknown

General Questions

Please answer the following questions related to **how you have felt over the past week.**

41. During the times when you **should** be fully rested, how often were you feeling tired?

   0. ❏ None of the time   1. ❏ A little of the time   2. ❏ Some of the time
   3. ❏ A good bit of the time 4. ❏ Most of the time   5. ❏ All of the time

42. Did you have trouble getting to sleep at night?

   0. ❏ Never   1. ❏ Rarely   2. ❏ Sometimes   3. ❏ Frequently

43. On the average, how many times during the night did you wake up (please circle one)?

   0   1   2 .3   4   5   6   7   8   9   10   > 10

44. How long did you sleep at night, on average?

   0. ❏ 0-2 hours   1. ❏ 2-4 hours   2. ❏ 4-6 hours
   3. ❏ 6-8 hours   4. ❏ 8-10 hours   5. ❏ 10-12 hours

45. Did you feel tired or sleepy during the day?

   0. ❏ Never   1. ❏ Rarely   2. ❏ Sometimes   3. ❏ Frequently

Continued on next page

Visual Analogue Rating Scales

Please mark on the line how you have felt over the past week.

46. *Average* amount of energy

None |————————————————————| High

47. *Highest* amount of energy

None |————————————————————| High

48. Generally speaking, how many hours per day do you experience this highest level of energy?

0. ❑ 0-0.5 hours   1. ❑ 0.5-1 hours   2. ❑ 1-2 hours
3. ❑ 2-3 hours   4. ❑ 3-4 hours   5. ❑ more than 4 hours

49. *Average* amount of general fatigue

None |————————————————————| Severe

50. *Highest* amount of general fatigue

None |————————————————————| Severe

Quality of Life Questions

Questions 51 - 54 are about how you feel and how things have been with you <u>during the past week</u>. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past week**:

51. Have you felt calm and peaceful?

0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
3. ❑ A good bit of the time   4. ❑ Most of the time   5. ❑ All of the time

52. Did you have a lot of energy?

0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
3. ❑ A good bit of the time   4. ❑ Most of the time   5. ❑ All of the time

Continued on back

53. Have you felt downhearted and blue?

       0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
       3. ❑ A good bit of the time   4. ❑ Most of the time   5. ❑ All of the time

54. During the past week, how often have you taken pain medication, including narcotics or over-the-counter medications?

       0. ❑ None   1. ❑ 1   2. ❑ 2-4
       3. ❑ 5-7   4. ❑ 8-10   5. ❑ >10

55. Can we put you on a mailing list for other upcoming studies: 0. ❑ No   1. ❑ Yes

END – Thank you for your participation

Diet (SUNSET) Subject Evaluation Form
Marshall-Blum LLC

Date: ___/___/___   ID#: _____

Visit: <u>4-Day</u>

1. How do you feel you have done with the fasting requirements over the last two days?

    Did not Comply =   0   1   2   3   4   5   6   7   8   9   = Totally Compliant

2. How do you feel you have done with the exercise requirements over the last two days?

    Did not Comply =   0   1   2   3   4   5   6   7   8   9   = Totally Compliant

3. How do you feel you have done with the supplement requirements over the last two days?

    Did not Comply =   0   1   2   3   4   5   6   7   8   9   = Totally Compliant

4. How do you feel you have done with the water consumption requirements over the last two days?

    Did not Comply =   0   1   2   3   4   5   6   7   8   9   = Totally Compliant

5. How much alcohol did you consume over the last two days? _____ (number of standard drinks)

6. How much nicotine did you use over the last two days? _____ (number of cigarettes or equivalent)

7. How much caffeine did you consume over the last two days? _____ (number of standard cups)

    If you consumed caffeine, please describe its amount and preparation: _____

_____

8. Would you use this weight management system again?

    0. ❑ No   1. ❑ Yes   2. ❑ Uncertain

9. Would you recommend this system to a friend?

    0. ❑ No   1. ❑ Yes   2. ❑ Uncertain

10. Side Effects: _____

Continued on back

11. Unexpected Benefits: _____

_____

12. Comments: _____

_____

_____

13. In general, how do you feel now compared to before you took the assigned product?

A lot worse =   -4   -3   -2   -1   0   1   2   3   4   = A lot better
                                                    Same

General Questions

Please answer the following questions related to **how you have felt over the past two days.**

14. During the times when you **should** be fully rested, how often were you feeling tired?

   0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
   3. ❑ A good bit of the time 4. ❑ Most of the time   5. ❑ All of the time

15. Did you have trouble getting to sleep at night?

   0. ❑ Never   1. ❑ Rarely   2. ❑ Sometimes   3. ❑ Frequently

16. On the average, how many times during the night did you wake up (please circle one)?

   0   1   2   3   4   5   6   7   8   9   10   > 10

17. How long did you sleep at night, on average?

   0. ❑ 0-2 hours   1. ❑ 2-4 hours   2. ❑ 4-6 hours
   3. ❑ 6-8 hours   4. ❑ 8-10 hours   5. ❑ 10-12 hours

18. Did you feel tired or sleepy during the day?

   0. ❑ Never   1. ❑ Rarely   2. ❑ Sometimes   3. ❑ Frequently

Continued on the next page

Visual Analogue Rating Scales

Please mark on the line how you have felt over the past two days.

19. _Average_ amount of energy

None ├───┤ High

20. _Highest_ amount of energy

None ├───┤ High

21. Generally speaking, how many hours per day do you experience this highest level of energy?

- 0. ❑ 0-0.5 hours
- 1. ❑ 0.5-1 hours
- 2. ❑ 1-2 hours
- 3. ❑ 2-3 hours
- 4. ❑ 3-4 hours
- 5. ❑ more than 4 hours

22. _Average_ amount of general fatigue

None ├───┤ Severe

23. _Highest_ amount of general fatigue

None ├───┤ Severe

END – Thank you for your participation

Diet (SUNSET) End of Study Form
Marshall-Blum LLC

Date: ___/___/___   ID#: _____

Visit: <u>7-Day</u>

1. Would you use this weight management system again?

    0. ❑ No   1. ❑ Yes   2. ❑ Uncertain

2. Would you recommend this system to a friend?

    0. ❑ No   1. ❑ Yes   2. ❑ Uncertain

3. Side Effects: _____

_____

4. Unexpected Benefits: _____

_____

5. Comments: _____

_____

_____

6. In general, how do you feel now compared to before you took the assigned product?

    A lot worse =   -4   -3   -2   -1   **0**   1   2   3   4   **= A lot better**
                                Same

General Questions

Please answer the following questions related to **how you have felt over the past two days.**

7. During the times when you **should** be fully rested, how often were you feeling tired?

    0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
    3. ❑ A good bit of the time 4. ❑ Most of the time   5. ❑ All of the time

Continued on back

8. Did you have trouble getting to sleep at night?

   0. ❏ Never   1. ❏ Rarely   2. ❏ Sometimes   3. ❏ Frequently

9. On the average, how many times during the night did you wake up (please circle one)?

   0   1   2   3   4   5   6   7   8   9   10   > 10

10. How long did you sleep at night, on average?

   0. ❏ 0-2 hours   1. ❏ 2-4 hours   2. ❏ 4-6 hours
   3. ❏ 6-8 hours   4. ❏ 8-10 hours   5. ❏ 10-12 hours

11. Did you feel tired or sleepy during the day?

   0. ❏ Never   1. ❏ Rarely   2. ❏ Sometimes   3. ❏ Frequently

Visual Analogue Rating Scales

Please mark on the line how you have felt over the past two days.

   12. *Average* amount of energy

   None |————————————————————————| **High**

   13. *Highest* amount of energy

   None |————————————————————————| **High**

14. Generally speaking, how many hours per day do you experience this highest level of energy?

   0. ❏ 0-0.5 hours   1. ❏ 0.5-1 hours   2. ❏ 1-2 hours
   3. ❏ 2-3 hours   4. ❏ 3-4 hours   5. ❏ more than 4 hours

15. *Average* amount of general fatigue

   None |————————————————————————| **Severe**

Continued on the next page

16. _Highest_ amount of general fatigue

None |——————————————————————————————————| **Severe**

Quality of Life Questions

Questions 17 - 20 are about how you feel and how things have been with you <u>during the past week</u>. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past week**:

17. Have you felt calm and peaceful?

    0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
    3. ❑ A good bit of the time   4. ❑ Most of the time   / 5. ❑ All of the time

18. Did you have a lot of energy?

    0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
    3. ❑ A good bit of the time   4. ❑ Most of the time   5. ❑ All of the time

19. Have you felt downhearted and blue?

    0. ❑ None of the time   1. ❑ A little of the time   2. ❑ Some of the time
    3. ❑ A good bit of the time   4. ❑ Most of the time   5. ❑ All of the time

20. During the past week, how often have you taken pain medication, including narcotics or over-the-counter medications?

    0. ❑ None   1. ❑ 1   2. ❑ 2-4
    3. ❑ 5-7   4. ❑ 8-10   5. ❑ >10

**END – Thank you for your participation**

Diet (SUNSET) Nurse Evaluation Form
Marshall-Blum LLC

Start Date: ___ / ___ / ___   Measured height: _____ ' _____ "   ID#:_____

Variable	Baseline	1-Day	4-Day	7-Day	Comments
Date (mm/dd/yy)	/ /	/ /	/ /	/ /	
Date & time of last meal					
Weight (lbs.)					
Time weight taken					
Blood pressure: Cuff S / L (right arm unless otherwise specified)					
Pulse (bpm)					
Respirations (rpm)					
Photo taken	■	Yes / No	Yes / No	■	
Photo number(s) (if applicable)	■			■	
Comments					

End

Diet (SUNSET) Exercise Log
Marshall-Blum LLC

Date: ___/___/___   ID: _____

Instructions: PLEASE FILL OUT THIS LOG FOR **EACH TIME THAT YOU EXERCISE** OVER THE 2 DAYS THAT YOU ARE TAKING YOUR ASSIGNED PRODUCT. Examples are listed below.

Date	Day of the Week	Exercise	Time	Comments
Example				
01/01/03	Saturday	Walking	20 min	Brisk walk
01/03/03	Monday	Swim	.30 hour	Aqua-Aerobics

END – Thank you for your participation

Diet (SUNSET) Nurse Checklist
Marshall-Blum, LLC

Please *initial and date* when each task is complete.

Initial Visit

_____ The potential subject has read and understands the informed consent document.

_____ The potential subject has initialed each page of the informed consent document.

_____ The potential subject has signed and dated the last page of the informed consent document.

_____ The subject has been offered, on a voluntary basis, before and after study photographs.

_____ The subject has signed and dated the supplemental photograph consent page OR has declined study photographs.

_____ The subject has completely filled out the Demographic Form.

_____ The subject has completely filled out the Initial Visit Form.

_____ The subject has been successfully physically examined.

_____ The potential subject medically qualifies for this study.

_____ The subject has been verbally instructed on the fasting and exercise requirements.

_____ The subject has been verbally instructed on the use of the product.

_____ The subject has received their Information Sheet.

_____ The subject has been instructed on how to report any problems.

_____ The subject has been instructed on how to report any changes in their medical condition.

_____ The subject has been scheduled to return to the clinic the evening before they wish to begin the diet (after their evening meal).

Continued on next page

Comments: _____

_____

1-Day Visit

_____   The subject has recently finished their evening meal.

_____   The subject has been successfully physically examined.

_____   The subject has had their study photographs taken OR has declined study photographs.

_____   The subject has received their assigned product.

_____   The subject has been re-instructed on the fasting and exercise requirements.

_____   The subject has been re-instructed on the use of the product.

_____   The subject has been offered an additional Information Sheet.

_____   The subject has been given their Exercise Log and understands how to fill it out.

_____   The subject knows that their next appointment needs to be in 3 days, in the morning, before consuming any food or drink.

Comments: _____

_____

4-Day Visit

_____   The subject has not consumed any food or drink this morning.

_____   The subject has been successfully physically examined.

_____   The subject has had their study photographs taken OR has declined study photographs.

_____   The subject has turned in their assigned product bottle.

_____   The subject has turned in and completed their Exercise Log.

_____   The subject has completely filled out the Subject Evaluation Form.

Continued on next page

_____ The subject understands that they are no longer required to take any more study product.

_____ The subject knows that their next appointment needs to be in 3 days and that this will be their last office visit.

7-Day Visit

_____ The subject has been successfully physically examined.

_____ The subject has completely filled out the End of Study Form.

_____ All of the subjects questions have been answered.

_____ The subject understands that this is their last office visit.

_____ The subject has been given their End of Study Letter.

_____ The subject has been given their free product and compensation check.

Comments: _____

_____

In the case of an Adverse Event

_____ The subject has been given detailed instructions on how to proceed.

_____ The subject has been contacted 1-week later and is on track.

_____ The Adverse Event is over.

_____ The subject is satisfied with the outcome of the Adverse Event.

Comments: _____

_____

END