APPROVED BY RCRC IRB: 17 MARCH 2006

EXPIRES: 27 FEBRUARY 2007

AN AGREEMENT TO PARTICIPATE IN A RESEARCH STUDY
INFORMED CONSENT

Sponsors:	Integrative Health Technologies, Inc.
Cities and States:	San Antonio, TX AlgaeCal International, Inc. (ACI) Las Vegas, NV
Protocol Number/Title:	1252006 "Evaluation of the Safety & Efficacy of the AlgaeCal® Bone-Health Plan"
Principal Investigator:	Joel Michalek, Ph.D.
Address of Study Site:	Health and Medical Research Centers 4940 Broadway, Suite 201 San Antonio, TX 78209 3632 East Indian School Road Phoenix, AZ 85018
Study Site Telephone Number and 24-hour Telephone number:	210-824-4200

Warning: You must be honest and complete in providing your medical history and reporting side effects. Giving false, incomplete, or misleading information about your medical history, including past and present medication use or failure to report side effects, could have very serious health consequences.

Study Overview

The U.S. Surgeon General's reported that people of all ages, including 85% of adolescent girls and 65% of boys, do not get enough calcium and nutrients for normal bone growth, which has placed America's bone health in jeopardy. To address this problem, the Surgeon General (SG) issued a "call to action" for people to improve their bone health with (1) improved nutrition, (2) increased exercise, and (3) bone health education. The Surgeon General points out that "you are never too old or too young to improve your bone health." However, while he asks people to increase their calcium and vitamin D, a February 2006 government-sponsored study of over 36,000 women found calcium and vitamin D were of little help in improving bone health. A reviewer of the study points out that "one message is clear: calcium with vitamin D supplementation by itself is not enough to ensure optimal bone health calcium with vitamin D supplementation is like the ante for a poker game: it is where everyone starts."

This research study is designed to respond to the Surgeon General's "call to action" by examining the extent to which bone health can be improved by following a bone-health plan. The plan incorporates the Surgeon General's three components, but goes beyond calcium and vitamin D by adding other bone-building nutrients and incorporating a pedometer-based program that has been shown to increase physical activity levels.

Participant Eligibility

A total of 400 people, 300 adults and 100 youth and adolescents aged 8 -18 will be enrolled in this study. Your eligibility for participation will be determined during your enrollment interview.

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Pregnancy: Individuals who are pregnant or breast feeding are not eligible to participate. If you become pregnant during the course of the study, you will be required to discontinue participation in the study.

Volunteers who are enrolled into the study will be assigned to one of 4 groups:
Group 1) Youth & adolescents (ages 8-18 years) with parent's consent
Group 2) Adults with no restrictions with regard to body weight or bone density. Priority will be given to adults of participating youth and adolescents.
Group 3) Adults who wish to improve their body composition (lean, fat and/or bone density) and agree to follow the "Living at Goal Weight" weight loss plan. There are no restrictions with regard to body weight or bone density.
Group 4) Adults who are currently taking glyconutrients at their own expense and who have previously received a DEXA test showing below average BMD.

The study falls generally into two phases. The most intense first study phase lasts for six months. The second phase of the study ends after 5 total years of participation. You should only volunteer to participate if you intend to complete the entire 5 year study.

Requirements
Note: For parents of youth/adolescents who agree to participate, you are agreeing to assist your child in completing the study requirements noted below. Because your child is not legally capable of giving "consent" to participate in the medical research study, you (as their guardian) will be required to give consent in order for them to participate. Your child must also indicate their willingness to participate (by giving his/her "assent").

If you choose to enroll in the study, you agree to the following:

- Undergo DEXA bone density tests (as described below under "DEXA") at the beginning of the study and at 90 days, 6-months, one year and five years.
- Undergo blood chemistry tests at beginning of study, 90 days, and six months. (optional for youth & adolescents).
- Complete Quality of Life questionnaires at beginning of study, 90 days, 6-months, one year and five years.
- Complete DAILY TRACKING FORMS: Daily tracking forms must be completed at the end of each day or the following day for the first six months of the study as described below under "Tracking Forms."
- Complete WEEKLY VISITS: To report to the Research Center no later than 5 working days after the end of each week for the entire 6 month first phase of the study to:
    - Turn in the previous week's tracking forms.
    - Obtain a scale weight, blood pressure and heart rate and to report any side effects.

The Supplements
The ingredients in each of the three cookies, the nutrition drink mix and *NutraFlavor* boosters followed by a listing of the ingredients in a 2-capsule serving of AlgaeCal and a 3-capsule serving a strontium citrate are shown in Appendix 1.

The nutritional supplements used in this study are not considered experimental, although they are being used as part of a research study. Each AlgaeCal capsule contains 180 mg calcium, trace minerals and 200 international units of vitamin D. The low-fat cookies contain the same calcium, trace minerals and vitamin D as two AlgaeCal capsules.

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Daily nutritional supplements to be taken are as follows:
Youth & adolescents Group 1: One low-fat calcium & mineral-supplemented cookie each morning and one each afternoon (with at least 3 hours between).
Adult Groups 2, 3, 4: Two AlgaeCal capsules or one low-fat calcium & mineral-supplemented cookie each morning followed by two AlgaeCal capsules or one low-fat calcium & mineral-supplemented cookie each afternoon (with at least 3 hours between). Additionally, three strontium citrate capsules (containing 2 mgs strontium total).
Group 3: Along with the "Living at Goal Weight" program, you will drink one low-fat shake with booster supplement packet daily.

Additional Supplements
Before starting the nutritional supplements, study subjects will be questioned about their current calcium intake (including calcium-containing antacids) and multivitamin with minerals intake. During the study you may take additional supplements as you wish and report any use of calcium supplements to the research center during your weekly check-ins.

Pedometer Use
You will be required to wear the pedometer and record your daily steps for the first six months of the study. Although strongly recommended, wearing the pedometer and recording daily steps for the remainder of the study is optional.

Tracking Forms
You will be asked to complete the tracking form at the end of each day but no later than the end of the next day. A copy of the form is in Appendix 2.

Costs to the Subject
All tests and the pedometer will be provided without charge. While we recommend you continue wearing the pedometer and recording your daily step totals throughout the study, this is required only for the first six months of the study. All supplements will be provided without charge during the first six months of the study only. While we recommend, but do not require, that you continue to take them after the first six months, you will have to purchase them at your expense. Your choice to purchase or not to purchase the supplements will have no bearing on participating in the remaining portion of the study. We will provide you with the address of a store in your area or a web site where you can purchase the supplements. Although we cannot assure you of the prices, our best estimate at this time is that the costs are as follows: one-month supply of AlgaeCal capsules = $29.00, one-month supply of strontium capsules = $29.00, two-week supply (one drink per day) of the nutrition drink mix = $19.50; Nutra-flavor Boosters = $0.95 per serving.

Study Procedures: A Checklist for Participation
If you meet the eligibility requirements for inclusion in the study and wish to be a participant, you will be expected to complete the steps listed below.

1. Read this Informed Consent in its entirety and review the supporting information in which you are interested, or ask questions to ensure you understand what will be expected of you in the study.
2. Review the form with your physician to ensure that you have no medical conditions that would prevent your participation.
3. Sign the Informed Consent; have it witnessed; complete the beginning questionnaires; and pick up your *Study Participant Notebook.*

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4. Adults only will be asked to complete the two (men) or three (women) questionnaires described in Appendix 2. Put our assigned participant number, not your name, on each one..
5. Schedule and complete the DEXA test.
6. Pick up a blood test requisition and a list of the drawing stations throughout the city. Fast for 12 hours (water only). Have your blood drawn at the Quest Diagnostics Laboratory of your choice. This procedure should take about 10 minutes.
7. Pick up the supplements you will be taking, the pedometer, and the daily tracking forms (including the glyconutrients tracking/rating form and the nutrition shake tracking/rating form if you are in Group 3 or 4).
   - Youth and Adolescents: Take two cookies each day, one in the morning and one in the afternoon or evening. Put the pedometer on in the morning and wear it during your waking hours. At the end of each day, complete the cookie rating form on the back of the tracking "checks", sign the front certifying that the information provided is accurate, and make the second check out to the organization to which you will be contributing. Record the number of steps shown on your pedometer, adding any "step equivalents" (see checkbook instructions) and press the yellow reset button.

   - **Adults**: The bone-building ingredients in one cookie are the same as in two capsules. Take two cookies or four calcium capsules each morning and afternoon indicating on the rating form how many of each you took. Additionally, take three of the white strontium capsules before retiring at night. At the end of each day, record the number of steps shown on your pedometer, adding any "step equivalents" (see checkbook instructions) and press the yellow reset button. For those participants following the *Living at Goal Weight Plan*, (Group 3) complete the Nutrition Shake tracking/rating form at the end of each day. For those participants taking glyconutritional supplements, (Group 4) complete the Glyconutrients tracking/rating form at the end of each day.

8. Turn in each week's tracking/rating forms to the research center within 5 business days of each completed week. At this check-in, you will obtain a self-administered scale weight, blood pressure and heart rate.
9. During the 11th week of the study, call the Research Center and schedule your next DEXA test.
10. In the week following the first 90 days of the study, complete the DEXA and blood test (remembering to fast 12 hours before the blood test) and the questionnaires.
11. After completing the tests, questionnaires and an end-of-study-critique, participants will be provided with the beginning and 90-day DEXA and blood test results as well as the financial incentives described below in "Payment for Participation."
12. Follow the same procedures outlined above in #4 through #11 for the next 90 days.

Participant Time Involved

The total time required for the first six months of the study is approximately 42 hours, which includes completion of the Informed Consent Form, the initial meeting with the research technician, all of the required tests, completion of all required questionnaires, daily tracking forms, weekly check-ins, and the final study critique, including travel and wait times. The total time required for the next six months is approximately 6 hours. The total time required for years 2-5 is a total of approximately 6 hours.

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DEXA Bone Density Scan

The DEXA test is an FDA-approved measure of body fat, lean and bone density and is now considered the "gold standard" for these measurements. The test provides these measurements for the entire body as well as for different regions of the body. It can aid in the reduction of osteoporosis and obesity by identifying specific problem areas and risk factors to aid healthcare providers in designing programs and making suggestions for medications and dietary supplements. There is no discomfort associated with taking the DEXA test. No special preparations, ingestion of radioisotopes, or collection of biological samples are required. It requires that you lie on a comfortable open table while the DEXA scans your entire body in 12-20 minutes. The test exposes you to 0.02 mR of radiation during each scan. This level of exposure can be compared to the 125mR/year that is normally received from non-medical background radiation. The amount of radiation to which you are exposed is 1/20th of what you would receive from a chest x-ray, or about the same amount of radiation received during an airline trip from New York to Los Angeles. The DEXA has been conducted on almost 500,000 people (we have performed over 20,000 tests) and no injuries have been reported as a result of taking the test. Extensive information on the risks, benefits and research on the DEXA test is contained in the *Study Participant Notebook* which will be provided to you upon completion of the Informed Consent.

Potential Risks to Participants

The risks associated with this study are considered minimal. In fact, any risk to which you may be exposed could be offset by the value of the blood and DEXA test reports you will receive. These tests will provide you with medical information that could make you and your health care provider aware of medical problems of which you have been previously unaware.

Some potential risks related to your involvement in this study include the following:

- Risk to Adults: It is helpful to understand the level of risk associated with a DEXA bone density scan (see below) by comparison with the natural background radiation exposure, which comes from within the body itself (natural occurring radioisotopes and from terrestrial sources (soil, rocks, building materials, radon), and from extraterrestrial sources (cosmic rays). **The average annual background radiation exposure associated with a DEXA scan is generally less than 1 day of natural background radiation exposure.** The National Council of Radiation Protection and Measurements has recommended maximum permissible radiation dose levels for various categories of individuals to be 50,000 mSv/yr. According to the Council, "The annual effective dose limit of infrequent exposure of the general public that would include children is 5,000 mSv/yr." Using estimates derived from total body irradiation, it is possible to calculate the increased risk of cancer associated with DEXA scans. Assuming that the risk of a fatal cancer in one's lifetime from a single exposure is approximately 8×10^{-8} mSv, one lumbar spine scan might increase the risk of cancer by less than 0.0001%.

- Risk to Adolescents: With regard to the potential risk to adolescents, a recent analysis entitled the "Effective Dose of Dual-Energy X-Ray Absorptiometry Scans in Children as a Function of Age" points out that: "With the increased use of DEXA to assess bone density and body composition in children, it is important to estimate the risk of adverse health effects associated with radiation exposure from a DEXA scan. This is particularly true for research studies when the DEXA scans are not performed as part of standard medical care and there is no potential direct benefit to the individual. **These researchers conclude that the average annual background radiation exposure associated with a DEXA scan is generally less than 1 day of natural background radiation exposure.** These calculations are based on the use of "fan-beam" measurements, as opposed to "pencil-beam" measurements which are to be used in this study (which have been found to result in 1/90th of the exposure found with fan beam systems). The National Council of Radiation Protection and Measurements has recommended maximum permissible radiation dose levels for various children and adolescents to be 5,000 mSv/yr. Therefore, using the

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Council recommendations results, even a series of 50 DEXA scans during a calendar year would be well below this annual limit for children."

- Loss of confidentiality concerning participant information: Confidentiality will be protected to the extent that is allowed by law. (See section entitled, "Release of Medical Records and Privacy"). The accidental sharing of your private health information may impact your future insurance or job possibilities.

- Allergic or other symptomatic reaction to product: Although the ingredient used in this product is considered "generally regarded as safe" (GRAS) by the U.S. Food and Drug Administration, there is always a chance of allergic reactions to the products. You should consult with your medical care provider prior to your involvement in the study. If you experience any allergic reactions or other adverse effects at any time during this study, you should discontinue product use, notify the researchers, and contact your medical care provider. In the rare event that you may require emergency care, you should seek care at an emergency room. Clearance from your medical care provider will be required before you will be permitted to continue in the study.

- Although generally well tolerated, possible side effects with calcium supplementation may include stomach discomfort and mild constipation.

- Emotional distress about answering sensitive questions: You may refuse to answer any questions used in the study surveys that cause you emotional distress due to their sensitive nature. However, if you experience such distress, please notify the researchers, and a list of community agencies that you may contact concerning this distress will be provided to you.

- Unknown effects: Although there are no known adverse effects from the supplement, testing or participation in this study other than those listed above, your personal medical history may present contraindications for your participation in a weight loss program. Therefore, you are asked to review your participation with your personal physician to insure there are no medical conditions that would prevent your participation. The researchers will try to prevent any problem that could arise because of this research. You should let the researchers know at once if there is a problem and they will help you. However, the Health and Medical Research Center does not provide medical services or financial assistance for injuries or other medical conditions that might occur because you are taking part.

- No studies are available to ascertain the known risks of the supplements used in this study to an unborn or developing baby. Since these risks are unknown, pregnant or breast-feeding women are not allowed to participate. [NOTE: we do not know if any small risk may exist].

Benefits

- There is substantial data to suggest that the bone health plan you will be following in this study may improve your bone health and provide other health benefits.
- You will receive five bone density tests which have a total value of approximately $1,000.00.
- You will receive three comprehensive blood chemistry tests. (Optional for adolescents) These tests can provide information on cardiovascular risk factors and information related to abnormal or symptomatic blood chemistries. The combined value of these three blood tests is approximately $1,300.00.
- You may be entitled to participate in future studies, some of which may begin immediately upon completion of this study.

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- Your participation may provide important scientific information that could support the Surgeon General's "call to action" for improving bone health.
- You are eligible to receive a maximum of $180.00 for yourself and a maximum of $180.00 to be donated to the charity or organization of your choice upon completion of the first six months of the study.

Release Of Medical Records And Privacy

This section explains how personal health information collected about you during this study may be used. Your personal health information includes, but is not limited to, information that was collected for your entry into the study and information that is collected during the study. This may include your name, social security number, and date of birth, address, medical records, and results of all the tests done during the study.

By signing this form, you authorize the study staff and the Study Doctor to use your personal health information to carry out the study and to disclose it, if needed, to RCRC IRB, and to the study sponsor, including people who work with the study sponsor to do the study. The study sponsor will only use the information to evaluate the study drug and the study's procedures. However, your entire medical record may be reviewed at the Study Doctor's office by the study sponsor and/or people who work with the study sponsor, and by regulatory agencies, such as the FDA. The purpose of these reviews is to assure the quality of the study, or for other uses allowed by law.

To maintain confidentiality of the data collected in this study, a participant code number will be assigned to you, and this code number will be used instead of your name in identifying and matching your testing and survey questionnaire data, as well as when your data are entered into a computer database. Participant data in hard copy and computer diskette format will be stored in a locked file cabinet at the Health and Medical Research Center in San Antonio, TX. Hard copy or computer diskettes containing participant identifiers will be stored separately from the other participant data. The researchers will store these identifiable data until no later than October 1, 2010 for potential use in future studies, at which time shredding will destroy the hard copy data, and the computer diskettes containing data will be reformatted to erase the data. In the event that the results of the study are published, no names or other identifying information will be included in the publication.

This permission to share your personal health information for this study does not have an expiration date. If you no longer want to share your personal health information, you may cancel your permission at any time by writing to the study staff and/or the Study Doctor.

If you cancel your permission after you have joined the study, you will be dropped from the study and the study staff and the Study Doctor will stop collecting your personal health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to maintain the dependability of the study. If you do not give permission for the release of your personal health information or if you cancel your permission, you will not be able to participate in the study.

The study sponsor will make every effort to keep your personal health information private and will not give it to anyone except as explained above.

You have the right to ask the Study Doctor to see and copy your personal health information related to the study. You also have the right to ask the Study Doctor to make changes to anything that is wrong and/or incomplete. However, to maintain the dependability of the study, you may not be able to see your study records until the study is over.

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The study sponsor will make every effort to keep your personal health information private and will not give it to anyone except as explained above. However, after the study staff or the Study Doctor releases your personal health information, federal privacy laws may not apply, although there may be other laws that protect your privacy

New Findings
During the study, you will be told of any important new findings about the study supplements. You may use this information in your decision to continue in the study.

Alternatives to Participation
This study is being done for research purposes only and your participation is voluntary. You may alternatively pursue some of the strategies listed in the *Study Participant Notebook.*

In Case of Research Related Injury
The Health and Medical Research Center does not offer to provide medical services or financial assistance for injuries or other medical conditions that might occur because you are taking part in this research.

Legal Rights
You do not waive any of your legal rights by signing this document.

Payment for Participation
In the first six months of the study, by completing all daily tracking forms, all weekly check-ins and all required tests, you personally can receive a maximum of $180.00--one dollar per completed form as long as you complete each form no later than 24 hours after the end of each day." By meeting the same requirements, you can also receive an additional $180.00 to be donated in your name to the charity or non-profit organization of your choice. "If you do not complete the forms in a manner consistent with the research requirements, your payment will be reduced accordingly, that is, $1.00 for each form not completed. You will receive these payments immediately upon completing the 90-day and 6-month testing requirements.

The researchers and research technicians are being paid hourly fees based on the amount of time spent in conducting the research.

Whom to Contact
You can contact the Study Doctor or staff

- for answers to questions about this research study,
- to report a research related injury, or
- for information about study procedures.

This consent form and study have been approved by RCRC IRB. RCRC IRB is a group of scientific and non-scientific people who review and approve or disapprove research involving people by following the Food and Drug Administration (FDA) rules. This group is also required by the FDA to do periodic review of ongoing research studies. Questions about your rights as a volunteer may be addressed to:

Chairman, RCRC IRB
706 West Ben White Blvd.
Austin, TX 78704
You may also call 888-200-5820 between 8 a.m. and 5 p.m. Central Standard Time.

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Voluntary Participation

Your participation in this study is voluntary, and you may withdraw from the study at any time without loss of any benefits to which you might be entitled.

If you have any questions about the research study, tests, supplements, your rights as a participant, or if you wish to withdraw from the study, contact Dr. Michalek, Dr. Kaats, or the research technicians at the Research Center in San Antonio (210) 824-4200 or in Phoenix (602) 790-6621.

Your part in this study may be stopped at any time without your being asked. The following people can stop the study:

- Integrative Health Technologies, Inc. (IHT) and AlgaeCal International, Inc. (ACI)
- RCRC IRB
- The United States Food and Drug Administration (US FDA)

You will be given a copy of this dated and signed consent form.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date
DO NOT SIGN AFTER 27 FEBRUARY 2007

_____
Address of Participant

Home Telephone:_____Day or Evening (please circle)

Work Telephone:_____Day or Evening (please circle)

Cell Phone:_____(to be used only if you cannot be reached at other numbers)

E-Mail address_____

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MINOR SUBJECT ASSENT STATEMENT (to be read aloud to subjects under age 18 years)

You are being asked to be in a research study which involves eating "healthy cookies" twice a day and measuring the number of steps you take every day for 6 months using a small device that you clip to your waist. You will also have special painless x-ray tests to measure your bone strength several times. After the first six months, you will only be required to have the special x-ray test repeated twice.

Your parent has decided that it is OK for you to be in the study, but it is also up to you.

If you want to be in study sign the line below at the left. If you do not want to be in study sign the line below at the right. Nothing bad will happen to you if you decide you don't want to be in the study.

Even if you agree to be in the study now, you can stop at anytime you want.

I want to be in the study

_____
Minor Subject Signature
DO NOT SIGN AFTER 27 FEBRUARY 2007

I do NOT want to be in the study

_____
Minor Subject Signature

FOR RCRC IRB USE ONLY	
Initial draft	tjm\main: 27Feb06
ejs\main:09Mar06	tjm\admin: 17Mar06

APPENDIX 1 – Nutritional Labels for study products

Oatmeal

Supplement Facts
Serving Size 1 cookie (16grams)
Servings per container: 1

	Amount per serving	% Daily Value
Calories	95	
Cals from fat	50	
Total Fat (g)	4.9	9%
Saturated Fat (g)	1.3	12%
Cholesterol (mg)	6.9	4%
Sodium (mg)	81.6	3%
Total Carbohydrates (g	8	2%
Dietary Fiber (g)	2.0	8%
Sugars (g)	2.5	
Protein (g)	2.0	
Vitamin A 2%	Calcium 31%	
Vitamin C 0%	Iron 3%	

Chocolate Chip Cookie

Supplement Facts
Serving Size 1 cookie (17grams)
Servings per container: 1

	Amount per serving	% Daily Value
Calories	99	
Cals from fat	43	
Total Fat (g)	4.8	7%
Saturated Fat (g)	2.2	11%
Cholesterol (mg)	10.4	3%
Sodium (mg)	35.5	1%
Total Carbohydrates (g	14	5%
Dietary Fiber (g)	2.1	9%
Sugars (g)	7.7	
Protein (g)	1.0	
Vitamin A 2%	Calcium 34%	
Vitamin C 0%	Iron 3%	

Peanut Butter Cookie

Supplement Facts
Serving Size 1 cookie (15grams)
Servings per container: 1

	Amount per serving	% Daily Value
Calories	98	
Cals from fat	53	
Total Fat (g)	5.9	9%
Saturated Fat (g)	2.3	12%
Cholesterol (mg)	12.7	4%
Sodium (mg)	81.6	3%
Total Carbohydrates (g	10	2%
Dietary Fiber (g)	2.0	8%
Sugars (g)	3.6	
Protein (g)	1.9	
Vitamin A 2%	Calcium 31%	
Vitamin C 0%	Iron 3%	

Body Composition Enhancer

Supplement Facts
Serving Size 1 Jar (28 grams)
Servings per container: 1

	Amount per serving	% Daily Value
Calories	94	
Cals from fat	17	
Total Fat (g)	1.9	3.0%
Saturated Fat (g)	0.43	2.1%
Cholesterol (mg)	4	1.3%
Total Carbohydrates (g	6	2.1%
Dietary Fiber (g)	5	17.2%
Sugars (g)	1	
Protein (g)	13	25.7%
Vit C (mg)	6	10.7%
Vit D (IU)	43	10.7%
Vit E (IU)	3	10.7%
Thiamin (mg)	0	10.7%
Riboflavin (mg)	0	10.7%
Niacin (mg)	2	10.7%
Vit B6 (mg)	0	10.7%
Folate (mg)	43	10.7%
Vit B12 (mcg)	1	10.7%
Biotin (mcg)	32	10.7%
Pantothenic Acid (mg)	1	10.7%
Calcium (mg)	172	17.2%
Iron (mg)	0	0.9%
Phosphorus (mg)	150	15.0%
Iodine (mcg)	16	10.7%
Magnesium (mg)	43	10.7%
Zinc (mg)	2	10.7%
Selenium (mcg)	8	10.7%
Manganese (mg)	0	10.7%
Chromium (mcg)	13	10.7%
Molybenum (mcg)	8	10.7%
Sodium (mg)	172	7.3%
Potassium (mg)	223	6.4%

INGREDIENTS: Protein Blend (Milk Protein Isolate, Whey Protein Isolate, Calcium Caseinate, Whey Protein Concentrate, Soy Protein Isolate, Soy Protein Concentrate, Egg White Powder), Glucomannan Soluble Fiber, Maltodextrin, Natural & Artificial Flavoring, Fructose, High Oleic Sunflower Oil, Natural and Artificial Flavors, Soy Lecithin, Microcrystalline Cellulose, Xanthan Gum, Cellulose Gum, Sodium Caseinate, Vitamin and Mineral Blend (Dicalcium Phosphate, Potassium Chloride, Magnesium Oxide, Potassium Citrate, Dipotassium Phosphate, Ascorbic Acid, d-Alpha Tocoperyl Acetate, Biotin, Sodium Citrate, Niacinamide, Zinc Oxide, d-Calcium Pantothenate, Manganese Sulfate, Folic Acid, Pyridoxine Hydrochloride, Thiamine Hydrochloride, Riboflavin, Chromium Polynicotinate, Cyanocobalamin, Vitamin D3, Potassium Iodide, Sodium Vitamin D3, Potassium Iodide, Sodium Molybdate, Sodium Selenite), Salt, Sucralose, Mono & Diglycerides, Enzymes.

NutraFlavor Booster

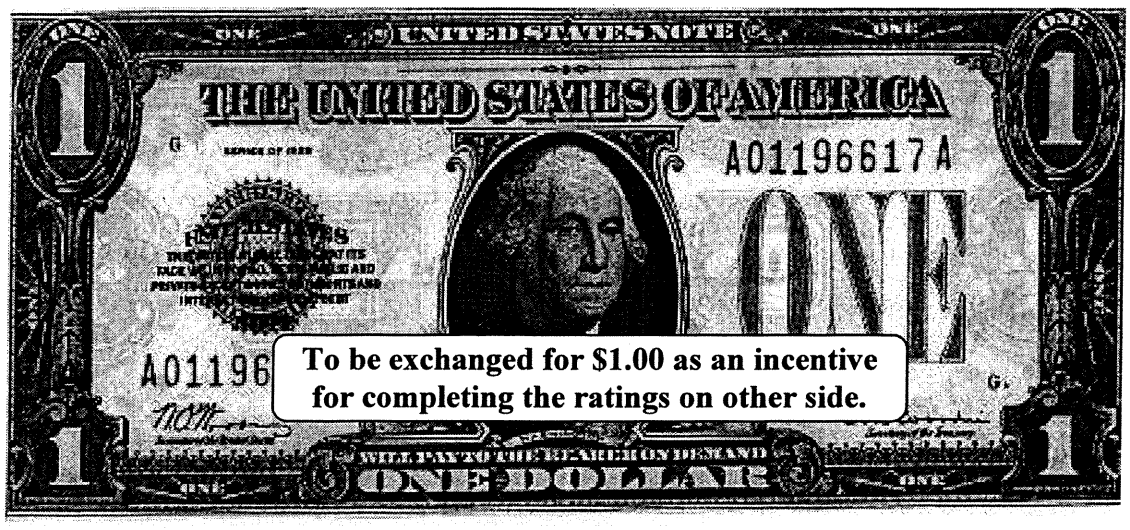
Supplement Facts
Serving Size 1 Jar (15 grams)
Servings per container: 1

	Amount per serving	% Daily Value
Calories	47	
Cals from fat	9	
Total Fat (g)	1	1.5%
Saturated Fat (g)	0	1.1%
Cholesterol (mg)	2	0.6%
Total Carbohydrates (g	3	1.1%
Dietary Fiber (g)	2	8.6%
Sugars (g)	0	0.0%
Protein (g)	6	12.9%
Vit C (mg)	3	5.4%
Vit D (IU)	21	5.4%
Vit E (IU)	2	5.4%
Thiamin (mg)	0	5.4%
Riboflavin (mg)	0	5.4%
Niacin (mg)	1	5.4%
Vit B6 (mg)	0	5.4%
Folate (mg)	21	5.4%
Vit B12 (mcg)	0	5.4%
Biotin (mcg)	16	5.4%
Pantothenic Acid (mg)	1	5.4%
Calcium (mg)	86	8.6%
Iron (mg)	0	0.4%
Phosphorus (mg)	75	7.5%
Iodine (mcg)	8	5.4%
Magnesium (mg)	21	5.4%
Zinc (mg)	1	5.4%
Selenium (mcg)	4	5.4%
Manganese (mg)	0	5.4%
Chromium (mcg)	6	5.4%
Molybenum (mcg)	4	5.4%
Sodium (mg)	86	3.6%
Potassium (mg)	112	3.2%

INGREDIENTS: Protein Blend (Milk Protein Isolate, Whey Protein Isolate, Calcium Caseinate, Whey Protein Concentrate, Soy Protein Isolate, Soy Protein Concentrate, Egg White Powder), Glucomannan Soluble Fiber, Maltodextrin, Natural & Artificial Flavoring, Fructose, High Oleic Sunflower Oil, Natural and Artificial Flavors, Soy Lecithin, Microcrystalline Cellulose, Xanthan Gum, Cellulose Gum, Sodium Caseinate, Vitamin and Mineral Blend (Dicalcium Phosphate, Potassium Chloride, Magnesium Oxide, Potassium Citrate, Dipotassium Phosphate, Ascorbic Acid, d-Alpha Tocoperyl Acetate, Biotin, Sodium Citrate, Niacinamide, Zinc Oxide, d-Calcium Pantothenate, Manganese Sulfate, Folic Acid, Pyridoxine Hydrochloride, Thiamine Hydrochloride, Riboflavin, Chromium Polynicotinate, Cyanocobalamin, Vitamin D3, Potassium Iodide, Sodium Vitamin D3, Potassium Iodide, Sodium Molybdate, Sodium Selenite), Salt, Sucralose, Mono & Diglycerides, Enzymes.

APPENDIX 2 Tracking Forms

Front side of rating forms



Reverse side of rating form

GROUP 1 TRACKING FORM			
Type of Cookie	[1] Number Taken	[2] Type of Preparation	[3] Taste & Texture
Chocolate Chip			
Peanut Butter			
Oatmeal			
# Steps taken today			
1 = Enter number of each kind eaten			
2 = Frozen, Refrig, Room Temp, Heated			
3 = Using rating scale of: Poor 1…2…3…4…5 Excellent			

GROUP 2 TRACKING FORM			
Type of Cookie	[1] Number Taken	[2] Type of Preparation	[3] Taste & Texture
Chocolate Chip			
Peanut Butter			
Oatmeal			
1 = Enter number of each kind eaten			
2 = Frozen, Refrig, Room Temp, Heated			
3 = Using rating scale of: Poor 1…2…3…4…5 Excellent			
# Steps taken today			
# AlgaeCal capsules taken			
# Strontium capsules taken			

GROUP 3 TRACKING FORM			
Type of Cookie	[1] Number Taken	[2] Type of Preparation	[3] Taste & Texture
Chocolate Chip			
Peanut Butter			
Oatmeal			
1 = Enter number of each kind eaten			
2 = Frozen, Refrig, Room Temp, Heated			
3 = Using rating scale of: Poor 1…2…3…4…5 Excellent			
# Steps taken today			
# AlgaeCal capsules taken			
# Strontium capsules taken			
# of Nutrition Shakes taken			
# of NutraFlavor Boosters			

GROUP 4 TRACKING FORM			
Type of Cookie	[1] Number Taken	[2] Type of Preparation	[3] Taste & Texture
Chocolate Chip			
Peanut Butter			
Oatmeal			
1 = Enter number of each kind eaten			
2 = Frozen, Refrig, Room Temp, Heated			
3 = Using rating scale of: Poor 1…2…3…4…5 Excellent			
# Steps taken today			
# AlgaeCal capsules taken			
# Strontium capsules taken			
NOTE: Group 4 participants must complete the Glyconutrient Tracker			

APPENDIX 3

Name: _____ Date: _____

Wellness Dysfunction Inventory

0=This is NOT a problem 1 =a MINOR problem 2 =a MAJOR problem 3 =a SEVERE problem

	Condition, disorder or symptom	*Rating*		*Condition, disorder or symptom*	*Rating*
1	Headaches		26	Irregular heartbeat	
2	Irritable bowel syndrome		27	Shortness of breath	
3	Arthritis		28	Constipation or diarrhea	
4	Premenstrual syndrome		29	Stomach gas or indigestion	
5	Recurring sinus infections		30	Feeling weak	
6	Tension fatigue syndrome		31	Eating too rapidly	
7	Recurrent anxiety		32	Eating after being full	
8	Recurrent depression		33	Embarrassed about overeating	
9	Insomnia		34	Depressed over eating habits	
10	Low self esteem		35	Depressed about my weight	
11	Binge eating		36	Difficult to stop eating	
12	Chronic tension		37	Worrying about the future	
13	Lack of energy		38	Unable to concentrate	
14	Food allergies		39	Forgetfulness	
15	Feeling under stress		40	Bad temper or quick to anger	
16	Cancer		41	Indigestion	
17	Prostate problems		42	Diabetes	
18	Overeating		43	Vomiting	
19	Stomach pain		44	Heartburn	
20	Back pain		45	Esophageal reflux	
21	Pain in arms, legs or joints		46	Control over my appetite	
22	Menstrual pain or problems		47	Ability to relax	
23	Chest pain		48	Heart disease	
24	Dizziness		49	Fibromyalgia	
25	Lupus		50	Other_____	

ATHRITIS DISCOMFORT/PAIN SCALE

1. Do you currently experience any pain or difficulties due to arthritis? **YES** **NO**
   (If you answered "NO" stop here and do not answer any questions below)

For those people experiencing pain or difficulty with any form of arthritis, please answer the following questions.

DURING THE PAST 90 DAYS:

2. How would you describe the arthritis pain you usually had?

Severe	Moderate	Mild	Very Mild	None
1	2	3	4	5

Use the following scale to answer items 3 – 6.

All Days	Most Days	Some Days	Few Days	No Days
1	2	3	4	5

3. How often did you have severe pain from your arthritis?

1	2	3	4	5

4. How often did you have pain in two or more joints at the same time?

1	2	3	4	5

5. How often did your morning stiffness last more than one hour from the time you woke up?

1	2	3	4	5

6. How often did your pain make it difficult for you to sleep?

1	2	3	4	5

Use the following scale to answer items 6 – 17.

Not A Problem For Me	Due Entirely To Other Causes	Due Largely To Other Causes	Due Partly To Arthritis And Partly To Other Causes	Due Largely To My Arthritis	Due Entirely To My Arthritis
0	1	2	3	4	5

How much of your problem in each area of health was due to your arthritis?

7. Mobility Level (example: do errands)

0	1	2	3	4	5

8. Walking and Bending (example: climb stairs)

0	1	2	3	4	5

9. Hand and Finger Function (example: tie a bow)

0	1	2	3	4	5

10. Arm Function (example: comb hair)

0	1	2	3	4	5

11. Self-Care (example: take bath)

0	1	2	3	4	5

12. Household Tasks (example: housework)

0	1	2	3	4	5

13. Social Activity (example: visit friends)

0	1	2	3	4	5

14. Support From Family (example: help with problems)

0 1 2 3 4 5

15. Arthritis Pain (example: joint pain)

0 1 2 3 4 5

16. Work (example: reduce hours)

0 1 2 3 4 5

17. Level of Tension (example: felt tense)

0 1 2 3 4 5

18. Mood (example: down in dumps)

0 1 2 3 4 5

DURING THE PAST 90 DAYS:

19. How often have you had to take MEDICATION for your arthritis?

All Days	Most Days	Some Days	Few Days	No Days
1	2	3	4	5

20. Did you see a doctor more than three times last year for any problem other than arthritis?

YES NO

FEMALE DISCOMFORT SCALE

Female Discomfort Scale (To be completed by Adult women only)						
NONE 0.....1.....2.....3.....4.....5.....6.....7.....8.....9.....10 HIGH						
	To be completed at:	Baseline	90 Days	6 Months	One Year	5 Years
	Menstruating (Yes or No):					
1	Overall energy level:					
2	Feeling depressed:					
3	Feeling anxious:					
4	Feeling bloated:					
5	Food cravings:					
6	Cravings for sweets:					
7	Difficulty controlling appetite:					
8	Feeling overwhelmed:					
9	Overall physical activity:					
10	Desire to eat:					
11	Feelings of hopelessness:					
12	Self-esteem:					
13	Keyed up or on edge:					
14	Sad or tearful:					
15	Interest in usual activities:					
16	Difficulty in concentrating:					
17	Overeating:					
18	Insomnia:					
19	Breast tenderness:					
20	Headaches:					
21	Joint or muscle pain:					
22	Difficulty in getting along with others:					
23	Difficulties in school or work:					
24	Feeling bloated:					
25	Positive outlook on life:					
	To be completed at:	Baseline	90 Days	6 Months	One Year	5 Years

ATTACHMENT I
NOT PART OF THE CONSENT FORM –
FOR SUBJECT INFORMATIONAL PURPOSES ONLY

THE INFORMED CONSENT AND INSTITUTIONAL REVIEW BOARD; THEIR ROLE IN PROTECTING SUBJECT RIGHTS

What is a consent form?
The Informed Consent document contains important information required by the United States regulations regarding the protection of human subjects. The informed consent has been reviewed and approved by an Institutional Review Board (IRB).

What is an Institutional Review Board (IRB)?
An Institutional Review Board (IRB) is a committee established to review, approve, and conduct periodic review of biomedical research involving human subjects. *The primary purpose of such review is to guarantee the protection of the rights and welfare of the human subjects.*

IRBs were established as the result of unfair treatment of human subjects. Prior to this, other committees existed as a requirement of the United States Public Health Service (USPHS) policy established in 1965. IRBs are regulated by the Food and Drug Administration and the National Institutes of Health (NIH).

What does an IRB mean to me?
The purpose of the IRB is to inform and protect human subjects through the information provided in the informed consent document. Therefore, the IRB is acting as a supporter for the research subject. This means that the IRB has the right and responsibility to ensure that the research subject is fully informed of the procedures involved in the study as well as the risks and other treatments that are available if participation in the study is refused.

How can I tell that an IRB has reviewed and approved this study?
The stamp on your study documents reflect that RCRC IRB has approved the study. It is a FDA requirement that the study design (protocol), informed consent, any advertisements, and other instructions to the subject (Subject Instructions) be reviewed and approved by an IRB.

RCRC, the IRB for this study
RCRC is an independent IRB, operated by PPD Development, but the board members are not employed by PPD Development. The board members are people who work in the Austin community. RCRC stands for Research Consultants' Review Committee.

FDA regulations require that the committee have at least five members with varying backgrounds to provide complete and adequate review of research activities. To fulfill these requirements the RCRC Board currently includes physicians, pharmacists, Ph.Ds., a toxicologist (someone who studies the harmful effects of chemicals), a psychologist, an oral surgeon, and lay members (non-scientific).

ATTACHMENT II
NOT PART OF THE CONSENT FORM – FOR SUBJECT INFORMATIONAL PURPOSES ONLY

Please read and keep this information for future reference.

Although study personnel may be available to answer study related questions, those pertaining to subject rights listed below should be addressed to the RCRC IRB at 512-685-5743 or 800-688-2132.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

What are your rights as a research subject?

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.