

# A Functional Food Product for the Management of Weight

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\*\* **Conflict of Interest:** Dr. Bell is has filed a patent on the product described in this review and works for the company that is marketing the product. Dr. Goodrick is currently conducting a clinical trial using the product described in this article.

**ABSTRACT:** More than half of Americans have a body mass index of 25 kg/m<sup>2</sup> or more, which classifies them as overweight or obese. Overweight or obesity is strongly associated with comorbidities such as type 2 diabetes mellitus, hypertension, heart disease, gall bladder disease, and sleep apnea. Clearly, this is a national health concern, and although about 30 to 40% of the obese claim that they are trying to lose weight or maintain weight after weight loss, current therapies appear to have little effect. None of the current popular diets are working, and there is room for innovation. With the advancing science of nutrition, several nutrients — low-glycemic-index carbohydrates, 5-hydroxytryptophan, green tea extract, and chromium — have been identified that may promote weight loss. The first two nutrients decrease appetite, green tea increases the 24-h energy expenditure, and chromium promotes the composition of the weight lost to be fat rather than lean tissue. These have been assembled in efficacious doses into a new functional food product and described in this review. The product is undergoing clinical testing; each component has already been shown to promote weight loss in clinical trials.

**KEY WORDS:** ingredients for weight loss, functional foods, low-glycemic-index carbohydrates.

## I. INTRODUCTION

More than half of adult Americans are overweight or obese. Public health officials recommend weight loss for those who are overweight and have associated medical conditions, and for everyone classified as obese.<sup>1</sup> Increases in body weight and body fat greatly increase the risk of adverse health consequences.

Despite the plethora of popular diet books, commercial programs, and the government's own attempt at teaching primary care practitioners how to help their patients to lose weight, the results are disappointing.<sup>2</sup> Even the shift in eating patterns to low-fat foods, especially those low in saturated fats to reduce the risk of heart disease, simply resulted in people taking in the same if not more

total calories, usually from eating more carbohydrates.<sup>3</sup>

The purpose of this article is to explain the rationale for the development of a new food product that can be used as an adjunct to current therapies. The ingredients in the product are described in terms of their clinical efficacy. Finally, a healthy, balanced deficit diet is described, which incorporates the food product as a twice-daily snack.

## II. THE IDEAL WEIGHT-LOSS DIET

The ideal diet should create a deficit of 500 to 1000 kcal per day and be aimed at achieving a weight loss of 1 to 2 lb per week.<sup>2</sup> It is com-

monly referred to as the “balanced deficit diet”. The goal is to decrease body weight by 10 to 15% and stay at that level for 6 months to a year before starting to lose more weight.<sup>4</sup> No diet is complete without an exercise and behavior change program, but these are beyond the scope of this review and are described elsewhere.<sup>2,5,6</sup>

Establishment of the correct daily energy intake goal is the first step in planning.<sup>2</sup> As a rule of thumb, overweight patients need about 22 kcal/kg. A sensible weight reduction plan would provide 500 kcal fewer per day, which would theoretically yield one pound per week of weight loss ( $500 \text{ kcal} \times 7 \text{ days} = 3500 \text{ kcal/week} = 3500 \text{ kcal/week} \div 3,500 \text{ kcal/pound body weight} = 1 \text{ pound per week}$ ). Thus, a 100-kg individual would require 2200 kcal per day for maintenance and 1700 kcal per day to induce weight loss. The most commonly used caloric values for weight-loss diets are 1200 kcal for women and 1500 kcal for men.

Once the total daily calorie needs are determined, the composition of those calories must be calculated and the micronutrient needs determined (Table 1). The guidelines in the table accord with the Dietary Guidelines for Americans 2000.<sup>7</sup> Use of the Food Guide Pyramid facilitates the selection of the correct number of servings and the serving size for all food groups.<sup>8</sup>

Besides using an energy-restricted diet to lose weight, patients are encouraged to consume foods that are lower in calories than the foods they usually have.<sup>2</sup> These include foods of low energy density<sup>9-10</sup> (e.g., fresh fruits rather than dried and vegetable soup rather than cooked vegetables) and the use of lesser amounts of fat, sugar, or both. For example, yogurt can substitute for sour cream, low-fat cheese for regular-fat cheese, and low-fat cold cuts for regular cold cuts. A sugar substitute (aspartame) has been shown to be an effective adjunct to a weight-control program for maintenance of reduced body weight administered by a multidisciplinary team of physicians, dietitians, nurses, and psychologists.<sup>11</sup>

Others recommend the use of meal and snack replacements.<sup>12-15</sup> Two long-term studies (27 months and 5 years) determined meal replacement diets helped participants lose weight, maintain their weight loss, and improve

biomarkers of disease such as significantly reducing blood pressure and plasma concentrations of triglycerides, glucose, and insulin.<sup>12-14</sup> Subjects participating in these studies reduced their total energy, total fat, and cholesterol intake. The structure of knowing what a meal or snack will be each day appears to be a key element in promoting behavioral change.<sup>14</sup> It reduces the number of decisions required for food choices aiding in reduction in energy intake.

### III. INGREDIENTS THAT PROMOTE WEIGHT LOSS

Recently, ingredients have been identified that promote weight loss curbing appetite,<sup>3,16,17</sup> and increasing 24-h energy expenditure.<sup>18-24</sup> The composition of the weight loss can be favorably modulated to be fat rather than lean tissue.<sup>25-27</sup> These ingredients are described below.

#### A. Curb Appetite: Carbohydrates and Fiber

Carbohydrate has the greatest influence on satiety of all the macronutrients. A system has been developed for predicting rises in blood glucose after ingestion of carbohydrate-containing foods: the “glycemic index”.<sup>28-30</sup> The glycemic index is the change in the area under the curve (AUC) for blood glucose 2 to 3 h after ingesting a portion of food containing 50 g of carbohydrates. This area is then compared with the reference area evoked after ingestion of 50 g of white bread or glucose.

The sources with low glycemic indexes and those that are fibers are the most effective in promoting satiety and weight loss because they cause the least rise in blood glucose and insulin and take longer to digest and to be absorbed than carbohydrates with high glycemic indexes.<sup>3,17,28-31</sup> Only low-glycemic-index carbohydrates and fiber are included in the food product. How these carbohydrates exert their effect on weight loss and health are described below.

**TABLE 1**  
**Composition of a Weight Loss Diet (Balanced Deficit Diet)\***

Nutrient	Contribution to total kcal	Notes
Protein	1.5 g/kg of desirable body weight	Nearly twice the normal protein intake, but necessary during restricted calorie intake
Fat	Not to exceed 30% of total energy intake	Less than 10% of the total kcal as saturated fats; use a mixture of monounsaturated and polyunsaturated fats
Carbohydrate	Remainder of kcal after protein and fat kcal needs have been met (i.e., at least 50% of the total kcal)	Use of foods rich in fiber and with a low glycemic index; avoid simple sugars
Micronutrients	100% of the Recommended Dietary Intake; a multivitamin is recommended when total kcal are less than 1,200	Goal difficult to achieve without multivitamin supplementation; some patients may also need calcium supplements

\*Source, references<sup>2,5</sup>

## **1. Glycemic Index/Fiber and Weight Loss**

Low-glycemic-index carbohydrates and fiber may be of benefit to people who lost weight and want to maintain it.<sup>32</sup> A study of moderately obese subjects suggested that low-glycemic-index foods may improve the physiologic adaptation to energy restriction during dieting and afterward, during maintenance. Basal energy needs were dictated by dietary composition (i.e., glycemic index of foods) during periods of energy restriction. Resting energy expenditure decreased less with diets rich in low-glycemic-index carbohydrates compared with eucaloric energy-restricted diets containing high-glycemic-index foods (4.6% vs. 10.5%;  $p < 0.04$ ). This is important because consumption of energy-restricted diets usually produces declines in energy expenditure, which slows weight loss unless even fewer calories are eaten. This often proves frustrating for the patients and results in them gaining weight. Inclusion of low-glycemic-index carbohydrates appears to override this concern and may promote weight loss easier than diets rich in high-glycemic-index carbohydrates.

## **2. Insulin Response and Weight Loss**

Insulin response may be more important than the glycemic response in weight loss, although the two are highly correlated.<sup>33</sup> Some foods (e.g., protein-rich and bakery products, which are rich in fat and refined carbohydrate) elicit a greater insulin response than glycemic response. Similarly, eating carbohydrate- and protein-rich foods at the same meal increases the postprandial insulin response.<sup>34</sup>

In obese patients with type 2 diabetes, use of a hypocaloric, low-insulin-response diet over 12 weeks was shown to significantly decrease fasting and 120-min stimulated insulin concentrations, whereas a typical balanced deficit diet had no effect.<sup>33</sup> More weight loss occurred during the low-insulin-response diet than with a standard weight-loss diet, but whether the difference was clinically significant is uncertain (95% CI: 0.14 – 5.75 kg). Examples of low-insulin-response foods

used in this study and not in the typical balanced deficit diet are papaya for orange juice, porridge oats for whole-wheat toast, and pasta and lentils for cottage cheese and whole-wheat bread. This study supports a role for low-insulin-response and low-glycemic-index foods to promote weight loss.

## **3. Fiber and Weight Loss**

The amount of dietary fiber consumed influences body weight. In a 10-year study of 2909 healthy subjects aged 18 to 30 years, the relationship between dietary fiber and cardiovascular disease was assessed.<sup>17</sup> The amount of dietary fiber consumed between the lowest quintile and the highest range was  $< 5.9$  g/1000 kcal and  $> 10.5$  g/1000 kcal. Weight decreased linearly between intakes of dietary fiber from the lowest to highest quintile — from 78.3 kg to 75.0 kg ( $p < 0.001$ ) for Whites and from 83.5 kg to 79.9 kg ( $p = 0.001$ ) for Blacks. Fiber consumption adjusted for BMI was inversely and significantly associated with serum insulin levels ( $p = 0.007$  for Whites;  $p = 0.01$  for Blacks). Fiber intake also predicted other cardiovascular risks. Higher fiber intakes were significantly associated with lower serum triglyceride concentrations ( $p < 0.05$ ) and higher high-density lipoprotein-cholesterol concentrations ( $p = 0.005$ ). In each case, fiber better indicated risk than total or saturated fat consumption, which historically was thought to be predictive of the disease.

Higher fiber intakes associated with less weight gain may be related to the lower fasting insulin levels observed during this study.<sup>17</sup> High insulin levels may cause alteration of adipose tissue physiology, shunting of metabolic fuels from oxidation to storage, and thereby increasing appetite. Fiber consumption may affect weight gain independently of insulin through its low energy density, which increases satiety and prevents weight gain. However, the intake of fat (i.e., a high-density food) was not predictive of weight gain, so energy density cannot fully explain the phenomenon. It is likely that fiber has a dual role in regulating weight: preventing hyperinsulinemia by decreasing circulating insulin levels directly, and increasing satiety because of its low energy

density. These two important actions do not occur when people consume low-fat, high-carbohydrate diets rich in high-glycemic-index carbohydrates.

From this study it is clear that over a 10-year period, those consuming foods with the lowest glycemic indexes (i.e., high fiber, high fat) gained less weight than those consuming high-glycemic-index diets (low fiber, low fat).<sup>17</sup> Fiber and low-glycemic-index foods are important for weight control and therefore should be included in diets of the obese or overweight. Only reducing the amount of fat consumed may not be sufficient to assure weight loss and long-term maintenance of weight loss.

#### **4. Mechanisms of Action of Low-Glycemic-Index Carbohydrates and Fiber**

The hormonal profile created from consumption of low-glycemic-index carbohydrates and fiber is a low glucose and insulin response and a high glucagon response, which are desirable.<sup>3</sup> High-glycemic-index carbohydrates produce the opposite effect (high glucose and insulin and low glucagon):<sup>3</sup> they promote the uptake of glucose into the muscle, prevent gluconeogenesis from occurring in the liver, and inhibit lipolysis, thereby denying the body access to two major fuels — glucose and fat. Thus, after consumption of high-glycemic-index carbohydrates, the hormonal state created is similar to what occurs with the lack of food for several hours — a decrease in blood glucose and free fatty acids that induce hunger.

In addition, the ingestion of high-glycemic-index carbohydrates is undesirable because, calorie for calorie, they elicit higher insulin levels and c-peptide excretion than low-glycemic-index carbohydrates.<sup>3</sup> This functional hyperinsulinemia may promote weight gain by preferentially directing nutrients away from oxidation in the muscle and toward storage as fat. Certainly, exogenous insulin used by patients with type 1 and some with type 2 diabetes has been shown to promote weight gain, so that the hyperinsulinemia induced by diet should create the same effect. Thus, these hormonal changes in response to a high-glycemic-index carbohydrate diet appear to lower circulat-

ing levels of metabolic fuels, stimulate hunger, and favor storage of fat.

#### **5. Risk Reduction and Glycemic Index/Fiber Intake**

Patients who are overweight or obese have an increased risk of developing several chronic diseases,<sup>5,35</sup> and several studies have shown that a diet rich in low-glycemic-index carbohydrates and fiber reduce the risk of developing them.<sup>36-39</sup> In these studies, sometimes glycemic load (the product of the glycemic index of a specific food and its carbohydrate content, representing the quality and quantity of the carbohydrate and the interaction between the two<sup>36</sup>) was assessed; other times whole-grain vs. refined grain intake was assessed. Most whole-grain products have lower glycemic indexes and more fiber than refined grains. Both measurements are reflective of the glycemic index of foods. In the future, it is likely that more attention will be played by health care professionals to monitoring the intake of low-glycemic-index-rich carbohydrates and fiber in their patients who need to lose weight.

The consumption of low-glycemic-index carbohydrates and fiber is associated with a reduced risk of developing diabetes,<sup>39</sup> CHD,<sup>36,37</sup> and stroke.<sup>38</sup> The risk of developing type 2 diabetes is related to the type of grain products consumed.<sup>39</sup> As part of the on-going Nurses' Health Study, 75,521 women aged 38 to 63 years with no history of heart disease or diabetes completed food frequency questionnaires, with special attention played to the amount of whole grains (e.g., dark bread, whole-grain cereal, popcorn) and refined grains (e.g., sweet rolls, cake, white bread) consumed. After a 10-year follow-up period, the investigators determined that there was a significant and inverse relationship between the consumption of whole-grain products and the development of type 2 diabetes. The relationship was more robust in women with body mass indexes over 25 kg/m<sup>2</sup>. Overweight and obese people appear to benefit from a diet rich in whole grains to avoid developing type 2 diabetes.

As part of the same on-going study, data were reanalyzed to evaluate the effect of the type of

grain consumed on the risk of developing CHD.<sup>37</sup> After a 10-year period, for increasing quintiles of whole-grain consumption, the risk of developing CHD decreased. These findings emphasize the importance of consuming diets rich in low-glycemic-index carbohydrates and fiber to reduce the risk of developing heart disease.

In a similar, subsequent study on the same group of subjects, the investigators evaluated the effect of glycemic load on the risk of developing CHD.<sup>36</sup> The same cohort of women was followed for 10 years, and a high dietary glycemic load was significantly and positively associated with the risk of developing CHD, after adjusting for other risk factors like smoking, age, and total energy intake, among others. The effect was greater for women with BMIs over 23 kg/m<sup>2</sup>. Classifying carbohydrates by glycemic load (i.e., index) rather than as simple or complex was a stronger predictor of this disease. This study provides further support for the inclusion of low-glycemic-index foods in the diet of those who wish not only to lose weight, but also to reduce their risk of heart disease.

Another condition related to whole grain and fiber consumption is stroke.<sup>38</sup> In the same cohort of women, whole-grain consumption was inversely related to the development of ischemic stroke, independent of other risk factors related to heart disease, such as the intake of saturated fats. Thus, consumption of whole-grain products, which are high in fiber and generally have low glycemic indexes, may be of benefit to overweight people to avoid developing a stroke.

## **B. Curbs Appetite: 5-Hydroxytryptophan**

Brain serotonin has an inhibitory effect on eating behavior.<sup>40</sup> Twenty-eight obese subjects (BMIs between 30 and 40 kg/m<sup>2</sup>) took 300 mg of 5-HTP three times a day 30 min before meals. There were no other dietary restrictions during the first 6-week period; then an energy-restricted diet of 1200 kcal was imposed during the second 6-week period. Significant weight loss was observed during both periods with the 5-HTP, but not in the control group (5%;  $p < 0.02$ ). Carbohydrate intake decreased by about 50% in the first

period; early satiety was observed in 100% of the subjects during the first period and in 90% during the second in the 5-HTP group.

This work suggests a role for amino acids in regulating food intake.<sup>40</sup> The brain neurotransmitter serotonin becomes available through the conversion of tryptophan to 5-HTP. Serotonin appears to influence both energy balance and the circadian patterns of eating (i.e., three times a day) by activating satiety neurons in the medial hypothalamus. Serotonin seems to interact antagonistically with norepinephrine to decrease appetite and carbohydrate consumption. No side effects occurred with 5-HTP at this dose, and no one dropped out due to any reported conditions.

## **C. Increases Energy Expenditure: Green Tea Extract**

As early as 2737 B.C., the Chinese Emperor Shen Nung discovered tea and hailed it as a miracle of natural medicine.<sup>18</sup> Since then, numerous reports in the scientific literature have identified its help in a variety of conditions, as protection against atherosclerosis, and as a means of preventing halitosis, prostate and breast cancer, and diarrhea.<sup>22</sup>

Recently, green tea has been shown to induce weight loss.<sup>24,41</sup> Ten healthy volunteers took green tea, caffeine in the same amount as contained in the green tea, and a placebo on different occasions.<sup>24</sup> Measurements were made of 24-h energy expenditure and fat oxidation. Relative to the placebo and to the caffeine alone, the consumption of the green tea extract resulted in significant increases in 24-h energy expenditure (4%;  $p < 0.01$ ) and in the 24-h respiratory quotient (RQ) (from 0.88 to 0.85;  $p < 0.001$ ). (A lower RQ [ratio of expired CO<sub>2</sub> to inspired O<sub>2</sub>] indicates fat oxidation because more O<sub>2</sub> is required in relationship to expired CO<sub>2</sub> during fat burning. The RQ of carbohydrate oxidation is 1:1 and fat is 0.7.) Twenty-four urinary catecholamines (e.g., norepinephrine) increased only with the green tea (40%;  $p < 0.05$ ).

The mechanism of action of the increased resting energy expenditure, and the fat oxidation must be independent of caffeine because these

changes did not occur with caffeine administration alone. However, this contradicts earlier reports where a single dose of 100 mg of caffeine increased resting metabolic rate by 3 to 4% ( $p < 0.02$ ) during a 150-min period in both lean persons and persons who were formerly obese.<sup>23</sup> Giving the same dose of caffeine every 2 h over 12 h increased energy expenditure even further (8 to 11%;  $p < 0.01$ ). It is not clear yet whether caffeine is as effective as green tea, but certainly the combination of the two has been shown to be effective.<sup>24</sup>

The mechanism for increasing energy expenditure by green tea has been postulated to be its flavonoid, and more specifically its polyphenolic, content.<sup>24</sup> One class of these compounds, the catechins, have been shown to inhibit catechol *O*-methyltransferase (COMT), an enzyme that degrades norepinephrine. Although there are numerous catechins in green tea, probably the most influential is epigallocatechin gallate (EGCG). This cannot be obtained in appreciable amounts from any other food source.

The inhibition of COMT by catechins allows norepinephrine to exert a prolonged influence on thermogenesis and fat metabolism. Both of these metabolic processes are controlled by the sympathetic nervous system via norepinephrine. The delay in degrading norepinephrine allows it to remain in the sympathetic synaptic cleft longer and there exert its effect. Caffeine also has an effect on norepinephrine by inhibiting phosphodiesterases and prolonging the life of cAMP in the cell. These actions coupled with the sustained effect of norepinephrine caused by EGCG affect thermogenesis.<sup>23,24</sup>

The effect of increasing energy expenditure by 4% over 24 h increases the contribution of the thermogenesis component to the total energy expenditure.<sup>23,24</sup> Typically, thermogenesis contributes 8 to 10% of the daily energy expenditure, and the addition of green tea increases that figure by 35 to 43% (75 to 100 kcal). Although seemingly small for a single day, the long-term effects are significant. An assumed lower caloric expenditure of 75 kcal per day theoretically would result in nearly 8 lb of weight loss per year. In addition, the green tea may also affect lipase activity, which itself may promote weight loss.

One little-explored aspect of green tea extract is that it has been shown *in vitro* to inhibit gastric and pancreatic lipases by 37%.<sup>41</sup> The green tea and the digestive lipases were mixed together at doses normally consumed and at physiologic concentrations. The green tea used here<sup>41</sup> was the same as that in the previous study, which showed increases in energy expenditure.<sup>24</sup> One weight-loss product on the market today (orlistat) induces weight loss by the same mechanism and has been proven to be efficacious.<sup>42</sup> At the very least, more work needs to be done to determine whether weight loss using green tea by blocking lipase activity can be achieved *in vivo*.

## **D. Preserves Lean Tissue during Weight Loss: Chromium Picolinate**

Dietary chromium is an essential trace element involved in potentiating the action of insulin.<sup>25</sup> Chromium deficiency results in impaired glucose tolerance, insulin resistance, and elevated blood glucose concentrations. Supplementation can reduce the severity of these symptoms. The National Academy of Sciences recommends daily intakes of 50 to 200  $\mu\text{g}$  chromium, but Americans consume less than that — men 60% and women 40%.

Improvement in insulin utilization may lead to reductions in body fat. Correcting insulin resistance may also have a positive effect on muscle mass by slowing its catabolism.<sup>25</sup> Obese, nondieting subjects (mean BMIs around 30  $\text{kg}/\text{m}^2$ ) were randomly assigned to take 200 or 400  $\mu\text{g}$  of chromium as picolinate, or a placebo in a beverage also containing protein and carbohydrate. After 72 days, 154 subjects completed the study. Weight loss was  $1.08 \pm 3.42$  kg in the group who consumed 200  $\mu\text{g}$  of chromium,  $1.4 \pm 2.93$  kg in the group receiving 400  $\mu\text{g}$  of chromium, and  $0.14 \pm 2.66$  kg in the placebo group.

Using underwater testing (displacement method) with residual lung volumes determined by helium dilution, differences were observed between the groups receiving chromium and the placebo group.<sup>25</sup> A body composition improvement index (BCI) was calculated — that is, the difference between the sum of loss of body fat

and gain in nonfat mass (positive attributes) and the sum of fat gained and lean mass lost (negative attributes). The BCIs for both chromium groups were significantly better than for the placebo group (for 200 µg of chromium  $p < 0.015$  and for 400 µg of chromium  $p < 0.0002$ ). Thus, even during periods of slow weight loss, the tissue lost was predominantly fat rather than lean during chromium supplementation.

Obese subjects (mean BMI =  $33.7 \pm 5.4$  kg/m<sup>2</sup>) who were actively dieting were also evaluated.<sup>26</sup> Subjects consumed a very-low-calorie diet for 8 weeks; they then received a maintenance diet for 18 weeks, during which they were randomized to 200 µg of chromium picolinate, 200 µg of chromium yeast, or a placebo. Weight loss was similar among the groups, and after 26 weeks only the chromium picolinate group showed an increase in lean body mass ( $p < 0.029$ ) vs. reduced lean body mass in the other two groups. Even during significant weight loss, lean body mass can be preserved with chromium.

Obese and overweight subjects ( $n = 122$ ) were randomly assigned to receive 400 µg of chromium picolinate or a placebo for 90 days while actively trying to lose weight.<sup>27</sup> Subjects kept records of calories consumed and the amount of physical activity they were engaged in. Both groups lost weight:  $2.88 \pm 3.5$  kg for the chromium group and  $1.81 \pm 2.99$  kg for the control group ( $p = 0.24$ ). The percentage of body fat decreased as well:  $2.07 \pm 3.2\%$  for the chromium group and  $1.53 \pm 2.8\%$  for the control group ( $p = 0.12$ ).

Using dual energy X-ray absorptiometry (DEXA) and underwater weighing, the supplemented group was shown to have lost more fat mass than the placebo group ( $p < 0.023$ ), but both groups did lose fat mass.<sup>27</sup> Correcting for differences in caloric intake and energy expenditure, the effect of chromium picolinate on the loss of fat mass and on the percentage of body fat was even greater ( $p < 0.001$  and  $p < 0.001$ , respectively). Corrected values for weight loss were  $7.79 \pm 9.7$  kg in the chromium group and  $1.18 \pm 2.99$  kg in the control group ( $p < 0.001$ ).

Chromium picolinate does not promote weight loss. Rather, during weight loss it seems to shift the composition of the weight loss to fat rather

than fat-free mass. Doses of 200 or 400 µg appear to be effective, and chromium as picolinate rather than bound to yeast appears to be preferable.

#### IV. THE FUNCTIONAL FOOD PRODUCT

We have taken a new approach to weight loss using clinically proven bioactive ingredients assembled in a nutritional supplement (Table 2). Each serving of the product contains 45 kcal and is most effective if taken as a structured snack mid-morning and mid-afternoon — two times identified as difficult for people trying to lose weight (personal communication, George L. Blackburn). Each serving of the product is an 8-ounce beverage, which contains the macronutrients, and one tablet, which contains the other nutrient additives. The product contains only food-grade nutrients in the correct and safe doses, and from the sources that, as clinical trials showed, induced weight loss. This format was chosen because liquids have been shown to promote satiety,<sup>9,10</sup> and structured snacks help patients lose weight and maintain it long term.<sup>12-15</sup> The other nutrients (green tea, 5-hydroxytryptophan, and chromium picolinate) were included in a tablet because they have a poor flavor when consumed in a beverage.

The macronutrient percentages in the product are similar to the composition of the balanced deficit diet (62% carbohydrate, 18% protein, and 20% fat).<sup>2,5</sup> The protein comes from a source of high biological value to promote protein synthesis.<sup>43</sup> Fat is from a blend of cottonseed and soybean oils. The key macronutrient component is carbohydrate, which has a greater influence on weight management than protein and fat. Eating the recommended two servings per day of the food product will provide 14 g of low-glycemic-index carbohydrates. Most patients consume at least 200 g of carbohydrates. Dietary carbohydrates contain a mixture of high and low glycemic indexes. However, patients who eat a diet containing more low-glycemic-index carbohydrates than high ones will have the best results.<sup>3</sup> This diet would include meals rich in vegetables, fruits, and legumes, moderate amounts of protein and healthful fats, and low intake of refined grain products, potatoes, and concentrated sugars.

**TABLE 2**  
**Nutritional Composition of the Food Product**

Nutrient	Amount/kcal/%kcal	Notes
<b>Beverage Portion:</b> Carbohydrate	7 g/28/62 3 g fructose <sup>31,44</sup> 1.8 g psyllium <sup>45-47</sup> 1 g barley <sup>28,31</sup> 1 g other	Low-glycemic carbohydrate sources and fiber to promote satiety and reduce the risk of developing chronic diseases of aging <sup>3,17,28-32,34,36-39,45-47</sup>
Protein	2 g/8/18 2 g whey protein	High biological value sources <sup>43</sup>
Fat	1.0 g/10/20 1 g cottonseed and soybean oils 0.1 g other	Polyunsaturated fatty acids
<b>Tablet Portion:</b> Green tea extract	75 mg caffeine and 135 mg epigallocatechin gallate	Shown to increase resting energy expenditure <sup>23-24</sup>
5-hydroxytryptophan	10 mg	Shown to decrease appetite <sup>40</sup>
Chromium picolinate	100 mcg	Shown to promote loss of body fat instead of lean tissue during weight Loss <sup>25-27</sup>

## A. Sources of Carbohydrate/Fiber

The carbohydrate components in the food product include the low-glycemic-index carbohydrates (fructose and barley) and fiber (psyllium). These promote satiety,<sup>3,16,17</sup> and their consumption is associated with weight loss<sup>17,32</sup> and fewer co-morbidities.<sup>36-39</sup>

### 1. Fructose

The main sweetening ingredient is fructose. This is the sugar commonly found in fruit, sweeter than ordinary table sugar (sucrose) derived from beet or cane sugars, and with a low glycemic index (glycemic index [GI]= 32).<sup>31,44</sup> Taken as part of a meal, fructose produces a smaller incremental rise in plasma glucose level than do sucrose, glucose, potato starch, or wheat starch. Each serving of the functional food product contains 3 g.

### 2. Psyllium

Psyllium husk fiber is a viscous, mostly water-soluble fiber prepared from blonde psyllium seed (*Plantago ovata*).<sup>45</sup> Psyllium, because it is a dietary fiber, promotes satiety and minimizes weight gain.<sup>46</sup> It also has been shown to reduce blood lipid concentrations and blood glucose levels.<sup>45-47</sup> Each serving contains 1.8 g.

### 3. Barley Flakes

Of the grains, some forms of barley have among the lowest glycemic indexes.<sup>28,31</sup> Pearled barley (GI = 36) and cracked barley (GI = 72) have lower glycemic indexes than sweet corn (GI = 78), rolled barley (GI = 94), and instant white rice (GI = 128). We have included pearled barley with its bran still on it, called “hullless barley,” so that the naturally occurring fiber remains. Thus, it provides a low glycemic source of carbohydrate and a source of fiber (1.5%), both of which are advantageous in maintaining good glucose and weight control. Each serving contains 1 g.

## B. Sources of the Other Ingredients

### 1. Green Tea

Two servings of the functional food product provides green tea extract in the exact amount previously identified to promote weight loss.<sup>24</sup> Each serving supplies 135 mg of EGCG and 75 mg of caffeine.

Some patients may have concerns about the use of caffeine to promote weight loss, but these are unfounded. First, the dose of caffeine offered by two servings of the product is 150 mg. This is not excessive when compared with the amount contained in other foods. Coffee has an average of 180 mg per 8-ounce cup, and a can (12 ounces) of cola contains 64 mg.<sup>48</sup> Similarly, a standard dose of a commonly used pain reliever (Excedrin) contains 130 mg, and a weight-loss product (Dexatrim) contains 200 mg. Second, at doses of 100 mg taken during the day, residual effects were not shown to have an effect at night, because the half-life of caffeine is only 3 to 3.5 hours.<sup>23,24</sup>

### 2. 5-Hydroxytryptophan

Each serving of the food product contains 10 mg of 5-hydroxytryptophan, which is lower than the 450 mg per serving shown to be clinically effective.<sup>40</sup> We have chosen to use the lower amount based on discussions with bariatricians and others who caution its use.<sup>15</sup>

### 3. Chromium Picolinate

Each serving of the food product contains 100 mcg of chromium. This corresponds to the lower end of the efficacious dose.<sup>25-27</sup> However, we assumed that those who use the product are obtaining another 200 mcg from the diet, thereby giving them the highest end of the efficacious dose.

## V. WEIGHT-LOSS MEAL PLAN USING FOOD PRODUCT

A sample meal plan of a balanced deficit diet incorporating the food product is presented in Table 3. Using the Food Exchange List at the

**TABLE 3**  
**Weight Loss Meal Plan Using the Food Product (~ 1200 kcal for Most Women)\***

Foods	Calories	Fat (g)	Exchanges†
<b>Breakfast</b>			
Whole wheat bread, 1 slice	80	0	1 bread/starch
Margarine, 1 pat	45	5	1 fat
Cereal, shredded wheat, 1/2 cup	80	0	1 bread/starch
Milk, 1%, 1 cup	90	2	1 milk
Coffee, 1 cup	0	0	free
<i>Mid-morning snack</i>			
Orange, 1	60	0	1 fruit
<b>FOOD PRODUCT</b>	45	1	½ bread/starch
<b>TOTALS</b>	400	8	
<b>Lunch</b>			
Turkey sandwich			
Whole wheat bread, 1 slice	80	0	1 bread/starch
Turkey, 2 oz.	110	5	2 lean protein
Lettuce, 1 leaf			
Tomato, 3 medium slices	25	0	1 vegetable
Mayonnaise,			

**TABLE 3 (continued)**

regular	45	5	1 fat
Water, 1 cup	0	0	free
<i>Mid-afternoon snack</i>			
Grapes	60	0	1 fruit
<b><u>FOOD PRODUCT</u></b>	45	1	½ bread/starch
<b>TOTALS</b>	365	11	
<b>Dinner</b>			
Salmon, 2 ounces	110	5	2 lean protein
Vegetable oil	45	5	1 fat
Baked potato, medium to large	160	0	2 bread/starch
Margarine, 1 pat	45	5	1 fat
Green beans,	25	0	1 vegetable
Carrots, ½ cup	25	0	1 vegetable
Iced tea, unsweetened, 1 cup	0	0	free
Water, 1 cup	0	0	free
<b>TOTALS</b>	410	15	
<i>Evening Snack</i>			
Milk, 1%, 1 cup	90	2	1 milk
<b>DAILY TOTAL</b>	1,265	36 (26% of total kcal)	

**TABLE 3 (continued)**

TOTAL EXCHANGES				Bread/Starch 6 Fruit 2 Milk 2 Protein 4 Vegetable 3 Fat 4
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\*Adapted from reference<sup>2</sup>

†Complete list contained in reference<sup>2</sup>

Food Exchange List	Carbohydrate (g)	Protein (g)	Fat (g)	Kcal
Vegetables (1/2 cup cooked; 1 cup raw)	5	-	-	25
Fruits (1/2 cup or 1 medium piece)	15	-	-	60
Protein (1 ounce)  Lean	-	7	2-3	55

**TABLE 3 (continued)**

Very lean	-	7	1	35
Medium	-	7	5	75
Milk (1 cup)				
Fat-free or very low-fat	12	8	-	90
Starches (1 slice; ½ cup cooked grains; ¾ cup dry cereal	15	3	-	80
Fats (1 tsp. regular fats; 1 tbs. reduced-fat items)	-	-	5	45

bottom of the table allows a patient to easily substitute a variety of foods with nearly identical calories and micronutrients. This gives sufficient variety to avoid boredom.

Although it appears to be well balanced, the diet does not meet the micronutrient needs for many of the vitamins and some of the minerals (e.g., calcium, zinc, iron). Thus, people following this 1200-kcal plan should take a multivitamin with minerals and calcium supplements to supply about 350 mg of elemental calcium.

## VI. SUMMARY

Obesity is of epidemic proportions in the U.S., affecting adults and now children in al-

most equal percentages. Millions are spent on trying to control weight, but few aids have been successful. Patients and practitioners welcome new products. We have developed a nutritional supplement that contains active ingredients to increase satiety, increase the rate at which calories and fat are burned, and cause fat instead of lean tissue to be lost. Each active ingredient is a food that has been clinically proven to work. To ensure efficacy, we have combined them in the correct amounts and from the same sources as those clinically studied. The product is most helpful if taken mid-morning and mid-afternoon as a healthy, structured snack. Besides its inherent efficacious components, it takes the guesswork out of choosing a snack.

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