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**Statement by
Atkins Nutritionals, Inc.
to the
US Food and Drug Administration
Obesity Working Group**

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The recommendations contained in this document are submitted on behalf of the Atkins Physicians Council (the "APC") in response to the six questions posed by the US Food and Drug Administration's (FDA) Obesity Working Group at its meeting on October 23, 2003. The mission of the APC is to provide guidance for the educational information products about the Atkins Nutritional Approach™ (ANA™) supported by Atkins Nutritionals Inc. ("ANI").

ANI's vision is to change the way the world eats to promote good health. The ANA™ has been validated by over 400 published studies in support of the scientific principles behind the ANA™ and in over 15 studies during the past three years, specifically on its safety, efficacy and health benefits. Today, the ANA™ is a nutritional plan that is finding increasing acceptance in many nations as people around the world suffer from health conditions resulting from the obesity and Type II diabetes epidemics.

Through the APC, ANI seeks to help consumers, medical professionals, researchers and policy-makers better understand the health benefits associated with a controlled carbohydrate nutritional approach. Some of these activities include:

- An aggressive schedule of new books on subjects that were important to Dr. Atkins including his *Atkins Diabetes Revolution* to be published towards the latter half of 2004.
- A national medical education program that will teach health care professionals the current science and the protocols behind the ANA™.
- A wide range of consumer education programs and materials that will be available online, through printed materials and through special events and programs.
- A nationwide initiative in cooperation with medical associations, schools, parent and teacher associations and government agencies to address the obesity and diabetes epidemics that are now threatening America's children.

The APC currently includes Stuart L. Trager, M.D., Mary C. Vernon, M.D., and Stephen B. Sondike, M.D. and will be expanding over the next year to include physicians from a range of diverse specialties. All three of the current members incorporate the ANA™ into their medical practices and are engaged in ongoing ANA™ research.

Dr. Stuart Trager will serve as chairperson of the APC. Dr. Trager is an orthopedic surgeon at Pennsylvania Hospital in Philadelphia and founder of Elite Health and Wellness, a medical practice that relies on the ANA™ as a treatment for wellness. Widely published he has also presented papers at numerous

national society meetings including the American College of Cardiology as well as the American Academy of Orthopedic Surgery.

Dr. Mary Vernon is one of the nation's leading experts in bariatric medicine. She has presented at national meetings on low carbohydrate diets and their effect on human metabolism. A member of the medical staff at Lawrence Memorial Hospital, Dr. Vernon is also the Director of the Skilled Rehabilitation Unit and Wound Care Team at Brandon Woods Retirement Community and Medical Consultant for Retirement Management Corporation, an affiliate of Life Care Services. She founded and now actively participates in the Obstetrics and Gynecology Clinical Rotation for Family Medicine residents. Dr. Vernon has spent many years presenting on a variety of health issues affecting women such as domestic violence, osteoporosis and weight loss and has also been published in the *American Journal of Medicine*.

Dr. Stephen Sondike is a nationally recognized expert on childhood and adolescent obesity and diabetes and was recently appointed as director of the New Kids Program for pediatric obesity at the Children's Hospital of Wisconsin in Milwaukee. Previously, he served as director of the Nutrition and Wellness Program in the Adolescent Health Center at Mount Sinai Medical Center in New York City. Dr. Sondike has been published in many prominent publications including the *Journal of Pediatrics* and the *Journal of Adolescent Health*.

1. What is the available evidence on the effectiveness of the various education campaigns to reduce obesity?

Obesity is epidemic in America in spite of current education campaigns.

We believe minimal evidence exists for comprehensive evaluation of current public obesity reduction campaigns. One thing is clear, however: according to the Centers for Disease Control (CDC), obesity is rampant and pervasive in America today. We believe that despite best intentions, the current educational campaigns utilizing the USDA "Food Guide Pyramid" as a guide to healthy eating combined with "low fat" nutritional advice are actually contributing to the growing girth of the American population.

Further, we suggest that the combination of this dietary advice and the aggressive advertising from the food industry has generated an American diet high in refined sugars and trans fat. The result, we believe, is the rampant epidemic of heart disease, diabetes and metabolic syndrome in our country.

With estimates from the CDC suggesting that nearly two-thirds of the American adult population is overweight or obese and one-third of the population is in the category of clinical obesity, it is clear that the magnitude of this problem deserves the government's full attention. Most alarming --

and most damning with regard to evidence on the ineffectiveness of the current educational campaigns to reduce obesity -- is the tripling of the prevalence of overweight and obesity in our adolescent population over the past 20 years, and the doubling of these values in our adult population (Prevention Makes Common "Cents," US Department of Health and Human Services, September 2003).

The statistics on sweetener consumption and obesity support the current efforts of the US government and emphasize that we need to act now, and act in a manner that will produce results. Caloric consumption has increased at least 300 calories per person per year, with nearly 46 percent coming from refined grains and 23 percent coming from added sugars (Food Review, Vol. 25, Issue 3, Economic Research Service, USDA, Putnam, J. Allshouse, J. and Kantor, I. page 2). There is no sound nutritional rationale for US sweetener consumption to have increased by 10 million tons from 1980 to 1999, and for high fructose corn syrup consumption to have quadrupled to 9.2 million tons during this time. A recent estimate published in the *Wall Street Journal* placed an unacceptable 36 to 40 percent of US consumption of carbohydrates in the form of sugar and sweeteners.

As many as 300,000 lives may be lost annually from obesity related medical causes. Lifespan is reduced on average by 20 years due to this diagnosis. The effects of a policy based on removing dietary fat and replacing it with carbohydrates transcend to the workplace as well, where estimates suggest \$20-30 billion are lost annually in productivity due to increased medical problems linked to obesity. In 1994, employees lost 39.3 million workdays due to obesity-related medical conditions. This represents a 50 percent increase from 1988 (Prevention Makes Common "Cents," US Department of Health and Human Services, September 2003).

Repeating the wrong message more loudly will not stem the US obesity epidemic. Education directed at changing the way people eat must be practical and recognize that 80 percent of those currently wishing to manage their weight are NOT following recommendations to eat less and exercise more. It is time to change the message, to incorporate emerging science and to support the kind of behavioral and lifestyle changes that can have a significant impact on this problem (Prevention Makes Common "Cents," US Department of Health and Human Services, September 2003).

We suggest that while there is not one nutritional approach that will work effectively for every single person, each scientifically validated nutritional approach deserves a "seat-at-the-table" and deserves to be shared as a viable alternative with the American public. A significant body of science has been published in the past three years that demonstrate that the ANA™, its

four phases and its emphasis on controlling carbohydrate intake and balancing the intake of healthy fats, is one such valid approach. We urge the FDA to support ANI's efforts to share the message of the scientifically proven weight loss and heart health benefits of controlled carbohydrate nutrition with the people of this country. (A full index of the scientific research can be found at www.atkins.com)

2) What are the top priorities for nutrition research to reduce obesity in children?

Recognizing the causes for childhood obesity is paramount to effect the necessary changes in this arena. The multifactorial nature of this epidemic is likely most easily appreciated in our children, who are less active and are consuming increasing amounts of nutrient-void food. They also are being more frequently bombarded with marketing for foods containing the greatest amounts of sugar and high fructose corn syrup. Therefore, we recommend research needs to be conducted in a number of areas, simultaneously, and suggest that the top priority for nutrition research to reduce obesity in children should include genetics, insulin action, and behavioral and environmental factors. We strongly encourage that the National Institutes of Health (NIH) fund research into these areas, and that the government support the efforts of independent research organizations investigating this area.

Basic science research into genetics and insulin action are very important in the management of the obesity in children. A clearer understanding of the importance of the impact of insulin and hyperinsulinemia on children's growth and the development of diseases such as type 2 diabetes is critical.

Although much research exists about behavior management of the child in the family constellation, more needs to be learned in the area of practical empowerment for children and families in regards to health issues. What are the barriers to implementation of healthy food choices once those healthy choices are known? How can exercise be functionally incorporated into activities of daily living? We know that children are extremely susceptible to portion size modification. To this extent, studies must address how food choices and the macronutrient composition of childhood diet can be modified to produce satiety -- or a sense of "fullness" -- and to encourage the lifelong dietary changes needed to have a real impact.

We also suggest that the federal and local governments should examine the effect of the placement of vending machines with non-nutritive selections in our public schools, as well as food industry sponsored texts and learning materials. Additional research could examine the impact of providing access

to vending machines with healthy food choices including protein. Also important is to address the bias, bullying and stereotyping of larger children at school, through the media and in physical education settings.

3) What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations of both?

ANI believes the FDA should consider the emerging research on the effects of dietary macronutrients in order to craft new and up-to-date recommendations for obesity. New evidence is available to indicate that high dietary carbohydrate loads - especially in combination with restricted fat - are actually increasing obesity rather than decreasing it, and may be increasing the risks of coronary heart disease, as well as diabetes, and other conditions through their effects on the triglyceride-HDL axis (Parks & Hellerstein, Am. J. Clin. Nutr. 2000; 71; 412-33). We believe that the FDA should review all the published science on controlled carbohydrate nutrition published in the past three years, all of which can be found at www.atkins.com.

There is tremendous potential to improve overall health through dietary and exercise intervention based upon the metabolic changes that coincide with even modest reductions in weight. Focusing on obesity without recognizing this potential does a great disservice to the many individuals who can be helped by taking a more active role in their health. The FDA should also encourage dietary supplements as an adjunct to good nutrition when their safety profile is acceptable.

Current literature supports increasing fiber intake and reducing glycemic load to reduce the risk of certain cancers, as well as diabetes and other health conditions. Additionally, reducing carbohydrate consumption has been shown to improve markers of inflammation (c reactive protein), which have been associated with increased risk of heart disease (Obrien, KD Division of Cardiology, University of Washington, Presented at the American Heart Association Scientific Sessions, November 19, 2000).

4) Are there changes needed to food labeling that could result in the development of healthier, lower calories food by industry and the selection of healthier, lower calorie foods by consumers?

ANI supports changes in food labeling that better inform the public on the nature of carbohydrates in their foods. For almost 30 years the American public has struggled with understanding and correctly utilizing nutritional labeling. During this time, they have also experienced two very different label formats for nutrition information used in labeling, packaging and promotion.

In spite of occasional confusion and frustration, most feel that progress has been made. Today's nutrition labels provide information that encourages both avoidance and consumption.

Generally, information on micronutrients such as vitamins and minerals, and the macronutrients, protein and fat, is based on well-established scientific methodology. The outstanding exception involves carbohydrates. Like most macronutrients, carbohydrates have been associated with good and bad health attributes. For labeling purposes, FDA and USDA have calculated the carbohydrate content of food by subtracting the sum of the crude protein, total fat, moisture and ash from the total weight of the product.

The FDA and USDA system essentially means that consumers have access to the actual chemical analysis and real data for all other nutrients but not for carbohydrates. Total carbohydrate is calculated only by difference. Since this definition lumps together everything that is not fat, water, crude protein, or ash, this method of carbohydrate determination includes many non-carbohydrate components such as gums, lignin, pectin, some dietary fibers, organic acids, and sugar alcohols.

The actual chemical definition of carbohydrate is structurally based and finite. Confusion arises because of the way the FDA has chosen to define a carbohydrate (only by differentiating from what it is not) is an analytical approach which lumps numerous different compounds under the "total carbohydrates" listing in today's Nutrition Fact Panel.

There also is no distinction on current labels between carbohydrates that are available for metabolism and those that are unavailable, like fiber. There is also no distinction made between carbohydrates that have an immediate and significant impact on blood glucose and plasma insulin (glycemic carbohydrates) and those that do not (non-glycemic carbohydrates).

For example, the FDA definition of "total carbohydrate" groups sugars and starches, which contribute 4 calories per gram and immediately increase blood glucose levels, with fiber, which contributes no calories and does not impact blood glucose. These structural and metabolic inconsistencies relative to the classic definition of "carbohydrate" argue powerfully for the existing labeling regulations to be reconsidered. As emerging science has shown us that these differences have clinical significance, changing this labeling can have a true impact in the war on obesity, and will support an educational campaign aimed at increasing the awareness of the health benefits and risks associated with the consumption of different types of carbohydrates.

5) What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

Many opportunities exist to improve the nutrition of America. Access to whole, fresh and minimally processed foods – especially adequate protein and leafy greens -- is the basis of such a plan. These foods should also be economically within the reach of even those on government food subsidy programs. This access, in combination with the information about how to choose from among these foods to build a healthy diet, will literally save millions of dollars in disease treatment costs.

Further research demonstrating the negative impact of total dietary carbohydrates and high glycemic load carbohydrates in the diet could help reduce the rate of development of diabetes and heart disease and their related treatment costs.

6) Based on the scientific evidence available today, what are the most important things the FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?

ANI believes the FDA should:

- Encourage decreased consumption of refined carbohydrate-rich, nutrient poor foods through efforts to improve education about the negative health impact of these macronutrients.
- Encourage healthy fat intake. Do not allow food manufacturers to substitute sugar for fat in foods and then allow them to be marketed as "healthy." Education is needed about the benefits of balanced fat intake, and to offset the "fat phobia" that has led to the development of calorie and sweetener laden "heart healthy foods." Recent FDA action to label trans fats represents an excellent move in this direction to help increase awareness about this dangerous sub-group of fat that has no known nutritional value and is associated with significant established health risks.
- Encourage adequate protein intake from a variety of sources as the basis of a "healthy" diet. Research has shown the positive effects that this produces with regard to lipids.
- Encourage intake of foods with as few additives as possible with the exception of mandated additives such as B vitamins in refined grains.
- Encourage government support for safe and economically accessible exercise or play areas in the local communities and mandated physical education in schools with programs that are supportive of all levels of skill and body types.