

2004-5775



NATIONAL CONSUMERS LEAGUE

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Honorable Lester M. Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Re: Misleading "Low Carb" Claims

Dear Dr. Crawford:

The National Consumers League (NCL) is deeply concerned with the recent proliferation of carb-related labeling and advertising claims. Given that none of these food claims are currently regulated by the Food and Drug Administration (FDA), many consumers are making purchasing decisions with incomplete information about exactly the type of food characteristics that should be driving healthy food choices. We urge both the FDA and the Federal Trade Commission (FTC) to take action now to defend consumers against such misleading labeling and advertising. We cannot afford to wait until completion of an anticipated rulemaking to define carbohydrate claims.

NCL is the nation's oldest consumer advocacy organization. Founded in 1899, NCL is a private, non-profit organization that represents the interests of consumers in the marketplace and the workplace. Nutrition, food labeling, and food safety have been longstanding concerns of NCL.

It is no secret that a "low carb" fad has swept the nation in the past two years, significantly altering the way many Americans eat. More than 1,500 food and beverage products making "low carb," "reduced carb," or similar claims have been introduced, creating an industry segment that is expected to reach \$30 billion in sales in 2004. Roughly 10% of Americans, about 26 million people, are on "low carb" diets.¹

While the "low carb" market segment booms, federal regulation of "low carb" claims appears to lag far behind. While FDA has indicated that it intends to initiate a rulemaking to define "low carb" and similar nutrient content claims, the effective date of any final rule is far in the future. Any final rule likely would not become effective until January 1, 2008, the uniform compliance date for food

¹ Daniel Kadlec, "Low-Carb Nation," *Time*, May 3, 2004.

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labeling regulations issued after December 31, 2004. Until FDA establishes definitions of “low carb” and “reduced carb,” these terms are essentially meaningless. What is the threshold for total carbohydrate content that qualifies as “low”? What reduction in total carbohydrate content is significant enough to qualify as “reduced”?

In the meantime, regulatory oversight of “low carb” claims is virtually nonexistent. Unlike their sister agencies, the U.S. Department of Agriculture’s Food Safety and Inspection Service (FSIS) and the Alcohol and Tobacco Tax and Trade Bureau (TTB), the FDA and FTC have not issued interim policies on carbohydrate claims. Without guidelines, manufacturers appear to be free to say virtually anything about the carbohydrate content of their products.

While FDA has issued two Warning Letters objecting to “low carb” claims that were clearly false,² the agency does not appear to be concerned about the large number of “low carb” products that make misleading claims. Two types of misleading label claims are of particular concern:

- “Low carb” and similar claims are often used on the labels of foods that have roughly the same number of calories as the traditional version of that food. Because the term “low carb” is associated in the public mind with weight loss diets, the use of a “low carb” claim for a food that has roughly the same number of calories as its traditional, non-“low carb” counterpart is misleading.
- Many food and beverage marketers are now using “net carb” labeling, even though this is a made-up term that is not grounded in sound science and has not been vetted by FDA, USDA and other regulatory bodies. “Net carbs” statements on food labels typically omit sugar alcohols, glycerin, and soluble fiber, even though these ingredients contribute calories and raise blood sugar levels. The term “net carbs” is used to designate carbohydrates that are not absorbed by the body and therefore do not affect blood sugar levels. However, while many food labels exclude sugar alcohols, glycerin, and soluble fiber from “net carbs,” these ingredients do contribute at least as many calories as carbohydrates and affect blood sugars. Even the Atkins Diet acknowledges that sugar alcohols, for example, contribute some calories and cannot be discounted entirely.³

² FDA has objected to “low carb” claims made for foods that had no significant reduction in total carbohydrate content as compared to comparable commercial products on the market. *See, e.g.*, Warning Letter to Peak Performance Foods, LLC, dated May 3, 2004.

³ Just this week, Atkins dropped its use of the “net carbs” measure calling it “imprecise” and conceding that sugar alcohols do raise blood sugar levels. *See S.*

“Net carbs” label statements that give consumers the incorrect impression that sugar alcohols, glycerin, and soluble fiber contain no calories and have no effect on blood sugars are misleading, if not outright false. Such misleading information is especially harmful to individuals with diabetes who must watch their calories very carefully. We also note that the recent report of the Dietary Guidelines Advisory Committee concluded that “glycemic index and/or glycemic load are of little utility for providing dietary guidance for Americans.”⁴

FDA’s and FTC’s lack of enforcement in this area has consequences. The widespread use of misleading claims, unchallenged by government regulators, contributes to consumer misunderstandings about carbohydrates and weight loss. Many consumers appear to believe that carbohydrates, not calories, cause weight gain. According to a recent survey by Opinion Research Corporation, 47 percent of Americans believe “low carb” diets produce weight loss without cutting calories.⁵ Almost half (45 percent) of Americans believe that eating “low carb” foods is good for the heart, while 36 percent believe “low carb” diets reduce risk of cancer. We believe that FDA’s inaction is viewed by many consumers as tacit approval of “low carb” diets, lending credence to misleading “low carb” marketing messages. More troubling, these popular misunderstandings are beginning to affect consumer eating behaviors. In the ORC survey, 50 percent of those on “low carb” diets said they are increasing their consumption of red meat, while 43 percent are cutting back on fruits. A recent study by the Mayo Clinic found that Americans are “eating more fat and cholesterol as ‘low carb’ diets grow in popularity.”⁶

Ellison, “Atkins Labels Will Drop Term ‘Net Carbs’,” *Wall Street Journal*, Oct. 6, 2004, p. B1.

⁴ *Report of the Dietary Guidelines Advisory Committee on the Dietary Guidelines for Americans, 2005*, p. 6. Glycemic index, which looks at the impact of food on blood sugar levels, is the theory underlying “low carb” diets.

⁵ This is not true. A review of the literature found that “low carb” diets offer no weight loss advantage over other diets that include carbohydrates and provide equal numbers of calories. Buchholz, AC, Schoeller, DA. Is a calorie a calorie? *Am J Clin Nutr* 2004; 79:899S-906S. There may be a short-term benefit to “low carb” diets, but this is attributable entirely to water loss and is not sustainable. Yang, MU, Van Itallie, TB. Composition of weight lost during short-term weight reduction. *J Clin Inv.* 1976; 58:722-730.

⁶ Reuters, “Experts: Americans eating more fat,” March 6, 2004.

NCL believes it is time for the FDA and FTC to act more decisively. With accumulating evidence that “low carb” diets are unhealthy,⁷ FDA and FTC should immediately establish guidelines for labeling and advertising of “low carb” products and insist that the food industry adhere to them:

1. FDA should issue an interim policy on “low carb” labeling, pending completion of a rulemaking defining such terms.

NCL believes that both FDA and the food industry need some guidelines regarding permissible and impermissible carbohydrate claims. An interim policy, in the form of a draft guidance for industry or draft Compliance Policy Guide, would regulate carb claims during the more than three years before any final rule defining such claims will go into effect. At the very least, an FDA interim policy should make it clear that misleading carb claims will not be tolerated. Where a food has a reduced carbohydrate content *vis a vis* comparable products on the market, but the food does not qualify as “low calorie” or “reduced calorie,” FDA should require that a “low carb” or similar claim must be accompanied by an appropriate disclaimer indicating that the product is not for weight control (*e.g.*, “not a low calorie food,” “not a reduced calorie food,” or “not for weight control”).⁸ An interim policy should either prohibit “net carbs” label statements, as TTB has done on alcohol beverage labels,⁹ or require that such calculations/statements must include sugar alcohols and other ingredients that contribute calories.

⁷ By restricting consumption of fruits, vegetables, whole grains, and dairy products, “low carb” diets can stress the kidneys and liver and increase risk of coronary heart disease and other serious health problems. A recent study concluded that very low-carbohydrate diets produce a high acid load on the kidneys that increases the risk of kidney stones and bone loss. Reddy, S, Wang, CY, Sakhaee, K, Brinkley, L, Pak, C. Effect of low-carbohydrate high-protein diets on acid-base balance, stone-forming propensity, and calcium metabolism. *Am J Kidney Dis* 2002; 40:265-274. The American Heart Association has warned that “low carb” diets may increase risk of heart disease, high cholesterol, stroke, diabetes, and certain kinds of cancer.

⁸ FDA regulations currently require that “sugar free” foods that do not qualify as “low calorie” or “reduced calorie” must bear a disclaimer to avoid misleading consumers. 21 C.F.R. § 101.60(c)(1)(iii)(B). This is because, without such a disclaimer, many consumers would think that a food labeled “sugar free” is intended for weight or calorie control. 56 Fed. Reg. 60421, 60437 (Nov. 27, 1991). Similarly, foods making “low carb” or similar claims should be required to bear a disclaimer if they do not qualify as “low calorie” or “reduced calorie.”

⁹ TTB Ruling 2004-1 (April 7, 2004).

2. FDA should immediately take enforcement action against misleading carb claims and label statements.

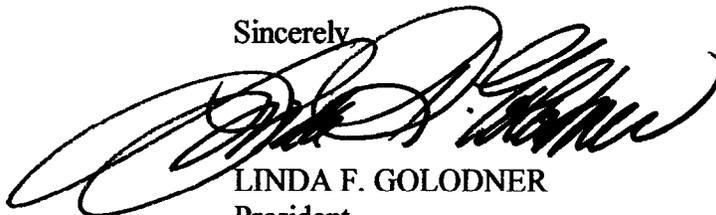
Even in the absence of an interim policy, FDA has the authority¹⁰ and the responsibility to take action against false or misleading carb claims. While FDA has taken limited action against false claims, it has not yet acted against misleading carb claims. NCL urges FDA to act immediately against the kinds of misleading carb claims described in this letter.

3. FTC should immediately take enforcement action against deceptive carb claims in advertising.

FTC should take immediate enforcement action against deceptive carb claims in advertising. As discussed above, these include “low carb” and similar claims for foods that do not qualify as “low calorie” or “reduced calorie” (unless accompanied by an appropriate disclaimer), and “net carbs” statements that omit sugar alcohols, glycerin, and soluble fiber. Vigorous oversight of “low carb” claims is consistent with existing FTC policy, which states that the Commission will “closely review” nutrient content claims not defined by FDA.¹¹ Given FTC’s longstanding interest in deceptive weight loss claims, NCL believes the Commission has an important role to play.

NCL believes that both FDA and FTC need to do a better job of protecting consumers from the misleading marketing practices associated with “low carb” products. We appreciate your consideration of this letter and look forward to prompt action.

Sincerely,



LINDA F. GOLODNER
President

cc: Mr. J. Howard Beales III, Director, Bureau of Consumer Protection,
Federal Trade Commission

¹⁰ See § 403(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 343(a)).

¹¹ FTC, Enforcement Policy Statement on Food Advertising, May 1994, p. 5.