THE
SUGAR ASSOCIATION

June 6, 2005

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: [Docket Number 2005N-0120] "Experimental Study of Carbohydrate Content Claims on Food Labels"

Dear Sir or Madam:

The Sugar Association, Inc. (Association) is pleased to provide comments on the Food and Drug Administration's (FDA) notice regarding proposed collection of information regarding the consumer study "Experimental Study of Carbohydrate Claims on Food Labels" (the Notice). The Association represents the United States sugar cane growers and refiners and sugar beet growers and processors. Association members account for over 90% of this country's sugar production. As the public information arm of the sugar industry, the Association disseminates scientifically substantiated information concerning sugar through public education and communication programs.

Necessity of the Study

FDA asks in the Notice "whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the

2005N-0120 C1

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information will have practical utility." The Association contends that the study is not necessary and will not have practical utility. There is no need for such a study in the absence of a demonstrated need, in light of scientific evidence or published authoritative statements by scientific bodies, to amend current FDA regulations by defining carbohydrate nutrient content claims. There are no published authoritative statements by scientific bodies as required in the regulations[1] that suggest that carbohydrate intakes need to be restricted. Although total calories intakes raise significant health issues, there is no significant evidence that carbohydrates as a percent of calories or recommended gram intakes are outside of the expectation for a healthful diet.

In the Nutrition Labeling and Education Act (NLEA), FDA clearly states that one of its objectives in developing a system of nutrient content claims is the need for the claim. Thus, FDA established as one of its guides "claims that are consistent with public health goals."[2] Without a body of scientific evidence of a negative health impact from carbohydrate (starches and sugars) intakes at current consumption levels or a clearly defined, evidence-based public health goal associated specifically with carbohydrate intakes, there is no justification to change FDA's original decision not to define carbohydrate nutrient content claims.[3] Therefore the proposed study is unnecessary.

The 2002 National Academy of Sciences, Institute of Medicine (IOM) report concluded that carbohydrate intakes ranging from 45% to 65% of calories are compatible with healthful diets[4]. The IOM also estimates that current US consumption of carbohydrates is within the recommended healthful range.[5]

Furthermore, because of FDA's authoritative position, its perceived endorsement of the "low carb" diet theory may contradict the advice given in the 2005 Dietary

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[1] The Food and Drug Administration Modernization Act of 1997 Section 403 (r) (2) (G) & (H).
[2] 58 Fed. Reg. No. 3 2319.
[3] 58 Fed. Reg. No. 3 2302, 2343.
[4] IOM, Dietary Reference Intakes: Energy, Carbohydrates, Fiber, Fat, Fatty Acids, Cholesterol, Protien, and Amino Acids, at 11-27.
[5] Id. at 6-23.

Guidelines for Americans (the 2005 Guidelines) and could undermine the impact of its "Calories Count" initiative.

> **Advice of the 2005 Guidelines**
>
> **"<u>When it comes to body weight control, it is calories that count—not the proportions of fat, carbohydrates, and protein in the diet</u>. However, when individuals are losing weight, they should follow a diet that is within the Acceptable Macronutrient "Distribution Ranges (AMDR) for fat, carbohydrates, and protein, which are 20 to 35 percent of total calories, 45 to 65 percent of total calories, and 10 to 35 percent of total calories, respectively. Diets that provide very low or very high amounts of protein, carbohydrates, or fat are likely to provide low amounts of some nutrients and are not advisable for long term use. Although these kinds of weight loss diets have been shown to result in weight reduction, the maintenance of a reduced weight ultimately will depend on a change in lifestyle. Successful and sustainable weight loss and weight maintenance strategies require attention to both sides of the energy balance equation (i.e., caloric intake and energy expenditure)."[6]**

The 2005 Guidelines key recommendation for carbohydrate intake is to increase fruit and vegetable intake and to increase whole grain intake.[7] Current FDA regulations assist consumers to identify which foods are good sources of fiber[8] and provide guidance for choosing foods rich in whole grains. FDA rules on calorie claims also assist consumers in comparing foods and choosing food that are lower in total calories.[9] Reducing total calories has been identified as a major public health goal.

There is thus no need to conduct a study to try to understand what consumers understand about a labeling claim involving carbohydrates in the absence of a determination that the information has significant health significance that might warrant such a claim.

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[6] 2005 Dietary Guidelines for Americans pg. 26.
[7] Id. 5 at 11.
[8] 21 CFR 101.54 (d) (1) (2).
[9] 21 CFR 101.60.

Practical Utility of the Study

Should FDA determine to conduct a study regarding nutrient content claims for carbohydrates, the agency should modify the proposed approach to ensure that the agency receives useful information regarding consumers' understanding of nutrient label claims in the principal display panel (PDP). The agency must determine whether the new food labeling will enable consumers to evaluate all aspects of the food item in order to judge whether or not the food provides a nutritional advantage over the reference product or over other products. Otherwise, the nutrient content claim, while truthful in and of itself, can result in a food label that is misleading in terms of product value and health effects.

The Food Drug and Cosmetic Act and the NLEA were enacted to assure consumers that they not only had a safe food supply but could make informed choices about the foods they consume because they are protected from deceptive practices.

The proposed study is designed to try to provide information on the consumers' perception when a nutrient is emphasized on the PDP with additional information such as footnotes about sugar, fat and calorie content. It does not, however, adequately explore consumer understanding of the potential changes to food items that enable manufacturers to make such claims. Although the study appears designed to determine consumer understanding when both the PDP and nutrition facts panel are presented, it is unclear whether the study will demonstrate whether, in the real world, consumers will actually make the effort to find and examine the fine print in the nutrition facts panel after seeing the PDP display a marketing claim related to carbohydrates content.

If the agency is going to consider permitting nutrient content claims regarding reductions in specific types of nutrients, the agency must recognize the necessity of placing important qualifying information on the PDP to ensure that consumers are not misled. As we know from currently permitted nutrient content claims, foods are

frequently reformulated to enable promotion based on such a claim by substituting ingredients to maintain bulk and taste. Ingredients such as fats and bulk fillers such as polydextrose or maltodextrin are often used to substitute for sugars that are more familiar to the consumer. The same can be expected for reductions in carbohydrates.[10]

We thus question whether this study will determine whether consumers will really examine and appreciate information that is not part of the marketing message on the PDP.

We also question whether the study will provide the agency with information on the most useful forms of disclosure on the PDP. We believe that the agency should assess whether a nutrient content claim regarding carbohydrates, such as "reduced carbohydrates," will be less misleading if coupled directly with a statement regarding other related characteristics of the product that may also have been modified. Marketing claims regarding reductions in specific sources of calories are inherently misleading in the absence of equally prominent information related to modifications to content of other sources of calories that may have more significant health consequences. Thus the study should consider whether consumers will be assisted in understanding nutrient content claims regarding carbohydrates by fairly balanced statements such as the following: "Reduced carbohydrates, ___% fewer [more] calories, ___% less [more] fat." Separating and thus deemphasizing the information on calories and fats is inherently misleading and the agency must fully examine the consequences of such separation.

The agency should also consider assessing in this study consumer understanding of "reduced" types of claims involving sugars and fats, by assessing such claims with and without immediately accompanying information on related modifications to caloric content and content of other significant nutrients. The agency should not consider

[10] This practice often leads to food items that contain ingredients unfamiliar and possibly, if informed, undesirable to consumers. An example of efforts to assist consumer education of changes to food products, Canadian regulations require aspartame, sucralose, acesulfame-potassium to be declared on the principle display panel. In nutrition labeling these ingredients are declared in milligrams. Canadian Food Inspection Agency, Guide to Food Labelling and Advertising Section VI – Nutrient Content Claims

nutrient content claims for carbohydrates in an information and policy vacuum, unrelated to claims for sweeteners and fats.

Furthermore, in order for this study to have practical utility FDA needs to explore whether consumers may be misled with regard to claims based on modifications to serving size. Claims can be misleading if the serving size is altered to achieve sufficient reduction in a particular nutrient. For example,

> Two multi-grain breads, one claiming to be "low carb," are made by the same company. The "low carb" bread has 60 calories per serving – 9 grams of carbohydrates – 15 calories from fat; the full carb bread has 90 calories – 18 grams of carbohydrates – 15 calories from fat; the full carb bread serving size is 38 grams and the low carb bread serving size is 27 grams. [See Attached Labels]

A thinner slice of bread to cut carbohydrates and calories may be positive but consumers are being misled. A study should be crafted to anticipate the multitude of variables that will confront the consuming public when or if these claims are approved.

Conclusion

If FDA promulgates rules and regulations for carbohydrate content claims, such action will be perceived as an implied endorsement of the "low carb" dietary theory, which lacks the scientific consensus, like that existing for saturated fat and calories, required for a public health goal.

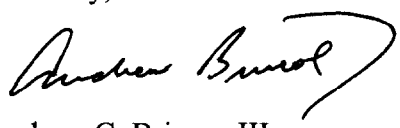
FDA's approval of carbohydrate nutrient content claims, which were originated and promoted as a diet concept by popular diet book authors, not nutrition science, will only further confuse and distract the consuming public from the important messages that "Calories Count."

Although the number of consumers participating in a "low-carb" lifestyle is declining, consumers that wish to choose this eating pattern already have sufficient information and choices, including checking for total carbohydrate content on food items, eliminating food items from their diets and decreasing portion size.

The Association asks that FDA give careful consideration before expending its resources on this study. We recommend that FDA reduce the number of approved nutrient content claims, which are inherently misleading when important qualifying information is not also presented with equal prominence on the PDP. Consumers already have too much conflicting information, and should be focused on information related to overall caloric content.

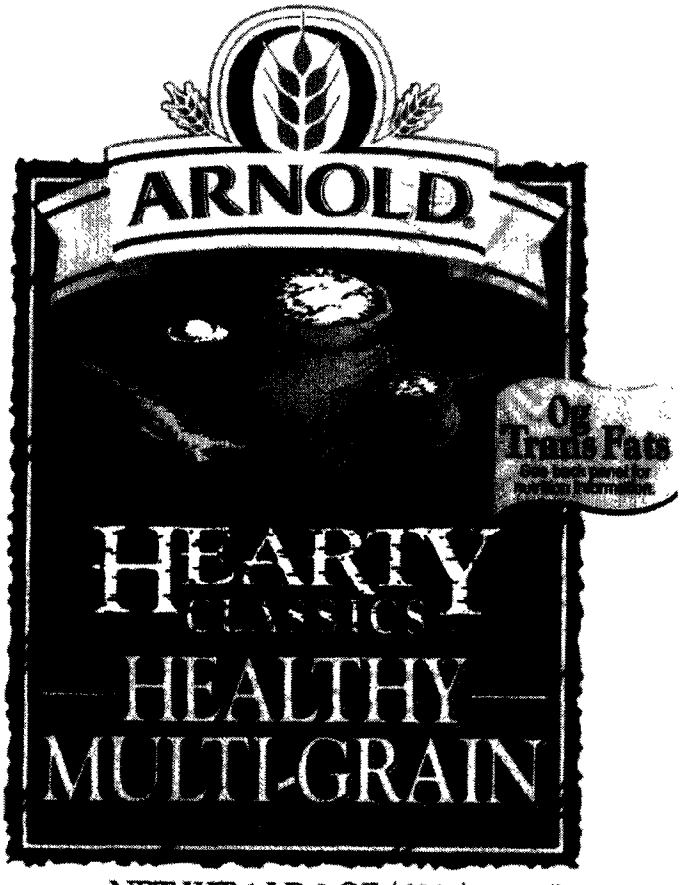
FDA should allow nutrient content claims only for nutrients that are deemed important to public health goals. The Association respectfully asks that the FDA rule to reject the Carbohydrate Content Claim petitions and decline to undertake an unnecessary study.

Sincerely,



Andrew C. Briscoe III
President & CEO

Cc:
David Adams, Esq.
Venable LLP
575 7th Street, N.W.
Washington, DC 20004



NET WT 1 LB 8 OZ (680g)

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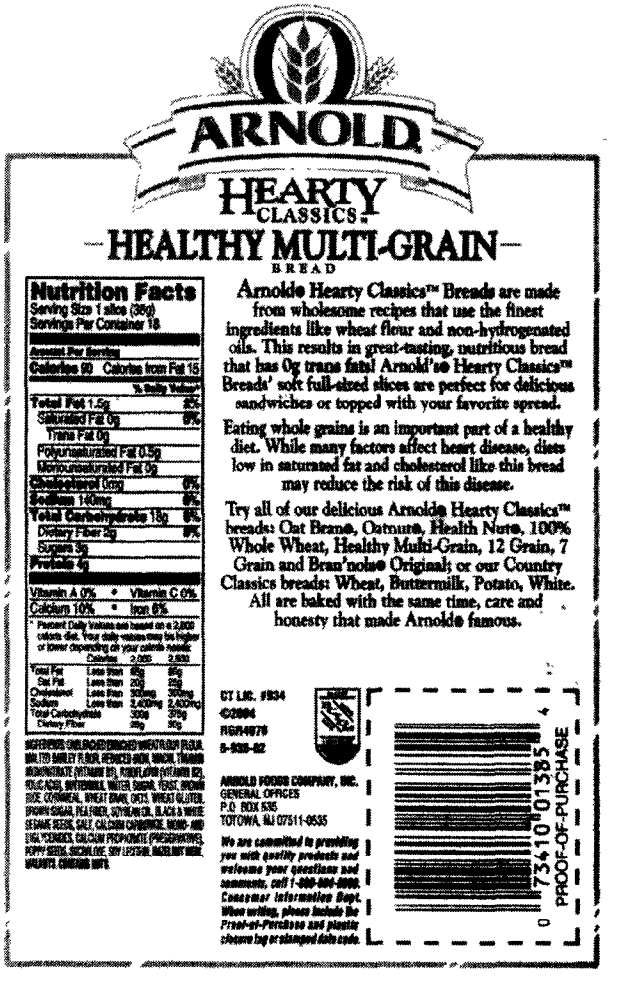

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BREAD

Nutrition Facts

Serving Size 1 slice (36g)
Servings Per Container 18

Amount Per Serving	
Calories 90	Calories from Fat 15
	% Daily Value*
Total Fat 1.5g	2%
Saturated Fat 0g	0%
Trans Fat 0g	
Polyunsaturated Fat 0.5g	
Monounsaturated Fat 0g	
Cholesterol 0mg	0%
Sodium 140mg	6%
Total Carbohydrate 18g	6%
Dietary Fiber 2g	8%
Sugars 3g	
Protein 4g	
Vitamin A 0% • Vitamin C 0%	
Calcium 10% • Iron 6%	

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

INGREDIENTS: UNBLEACHED ENRICHED WHEAT FLOUR (FLOUR, MALTED BARLEY FLOUR, REFINED OATS, WHOLE, TRIMMED MONONITRATE, RIBOFLAVIN, FOLIC ACID), WHOLE GRAIN BLEND (WHEAT BRAN, RYE FLAKES, BUTTERMILK, WATER, SUGAR, YEAST, WHOLE RICE, CORNMEAL, WHEAT BRAN, OATS, WHEAT GLUTEN, BROWN SUGAR, FLAXSEED, SOYBEAN OIL, BLACK & WHITE SESAME SEEDS, SALT, CALCIUM CARBONATE, MONO- AND DIGLYCERIDES, CALCIUM PROPIONATE (PRESERVATIVE), POPPY SEEDS, LECITHIN, SOY LECITHIN, HAZELNUT MEAL, WALNUTS, CINNAMON.

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Eating whole grains is an important part of a healthy diet. While many factors affect heart disease, diets low in saturated fat and cholesterol like this bread may reduce the risk of this disease.

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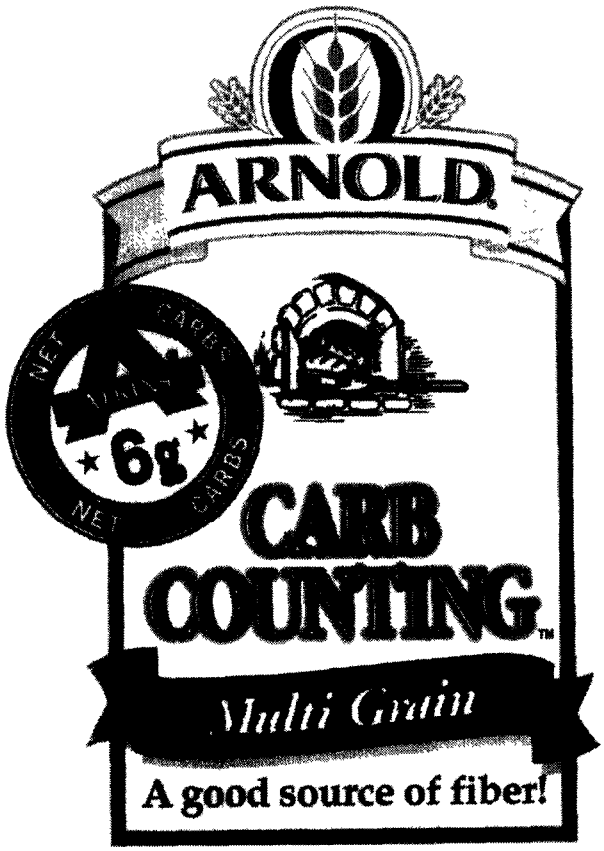

Ⓤ PARVE

NET WT 20 OZ (1 LB 4 OZ) (567g)

Cholesterol 0mg	0%	0%
Sodium 220mg	9%	12%
Potassium 80mg	2%	7%
Total Carbohydrate 22g	7%	9%
Dietary Fiber less than 1g	3%	3%
Sugars 4g		
Other Carbohydrate 18g		
Protein 7g	3%	13%
Vitamin A	15%	20%
Vitamin C	35%	35%
Calcium	0%	15%
Iron	45%	45%
Vitamin E	35%	35%
Thiamin	35%	40%
Riboflavin	35%	45%
Niacin	35%	35%
Vitamin B_6	100%	100%
Folic Acid	100%	100%
Vitamin B_{12}	100%	110%
Phosphorus	6%	20%
Magnesium	4%	8%
Zinc	6%	8%
Selenium	10%	10%

* Amount in cereal. One half cup of fat free milk contributes an additional: 40 calories, 65mg sodium, 6g total carbohydrate (6g sugars), and 4g protein.

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Saturated Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram: Fat 9 • Carbohydrate 4 • Protein 4

Ingredients: Rice, wheat gluten, sugar, defatted wheat germ, salt, high fructose corn syrup, dried whey, malt flavoring, calcium caseinate.

Vitamins and Minerals: Ascorbic acid (vitamin C), alpha tocopherol acetate (vitamin E), reduced iron, niacinamide, pyridoxine hydrochloride (vitamin B_6), riboflavin (vitamin B_2), thiamin hydrochloride (vitamin B_1), vitamin A palmitate, folic acid and vitamin B_{12}. To maintain quality BHT has been added to the packaging.

CONTAINS WHEAT AND MILK INGREDIENTS.

Exchange: 1½ Carbohydrates

The dietary exchanges are based on the *Exchange Lists for Meal Planning*, ©2003 by The American Diabetes Association, Inc. and The American Dietetic Association.

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Kellogg's® Special K® for a low carb lifestyle

Nutrition Facts

Serving Size 3/4 Cup (29g/1 oz.)

Servings Per Container About 13

Amount Per Serving	Cereal	Cereal with 1/2 Cup Vitamins A&D Fat Free Milk
Calories	100	140
Calories from Fat	30	30
		% Daily Value**
Total Fat 3g*	5%	5%
Saturated Fat 0.5g	3%	3%
Trans Fat 0g		
Cholesterol 0mg	0%	0%
Sodium 110mg	5%	8%
Potassium 320mg	9%	13%
Total Carbohydrate 14g	5%	7%
Dietary Fiber 5g	20%	20%
Sugars 2g		
Other Carbohydrate 7g		
Protein 10g	12%	20%
Vitamin A	15%	20%
Vitamin C	35%	35%
Calcium	4%	15%
Iron	45%	45%
Vitamin E	35%	35%
Thiamin	35%	40%
Riboflavin	35%	45%
Niacin	35%	35%
Vitamin B_6	35%	35%
Folic Acid	35%	35%
Vitamin B_{12}	35%	45%
Phosphorus	20%	30%
Magnesium	15%	20%
Zinc	8%	10%
Selenium	10%	10%
Copper	6%	6%

* Amount in cereal. One half cup of fat free milk contributes an additional 40 calories, 60mg sodium, 6g total carbohydrate (6g sugars), and 4g protein.

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.

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Total Fat	Less than	65g	80g
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Sodium	Less than	2,400mg	2,400mg
Potassium		3,500mg	3,500mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram

Fat 9 • Carbohydrate 4 • Protein 4

Ingredients: Wheat bran, soy grits, rice, wheat gluten, soybean oil, whole grain wheat, soy protein isolate, sugar, salt, high fructose corn syrup, malt flavor, natural and artificial flavor, ascorbic acid (vitamin C), sucralose, alpha tocopherol acetate (vitamin E), reduced iron, niacinamide, pyridoxine hydrochloride (vitamin B_6), riboflavin (vitamin B_2), thiamin hydrochloride (vitamin B_1), vitamin A palmitate, folic acid and vitamin B_{12}.

CONTAINS WHEAT AND SOYBEAN INGREDIENTS.

Exchange: 1 Carbohydrate

The dietary exchanges are based on the *Exchange Lists for Meal Planning* ©2003 by The American Diabetes Association, Inc. and The American Dietetic Association.

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