



June 7, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
rm. 1061
Rockville, MD 20852

RE: Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Carbohydrate Content Claims on Food Labels
Docket No. 2005N-0120

The Calorie Control Council (the “Council”) is an international association of manufacturers of low/reduced calorie, low/reduced fat, and light foods and beverages. Companies making the alternative sweeteners, fat replacers and low-calorie bulking agents for these products are also members of the Council. A number of these sweeteners and low-calorie bulking agents are carbohydrates.

Since 1978 the Council has conducted surveys to gauge public opinion on low-calorie foods and beverages. Reduced fat products were introduced into Council surveys in 1991 and the Council began referring to the combined category of low-calorie, sugar-free and reduced or low-fat products as “light” foods and beverages. Surveys are designed to show trends from earlier studies. The most recent survey, conducted in 2004, included questions on carbohydrates.

The Council’s 2004 Light Products Usage and Weight Control Habits Survey was conducted via telephone. Qualified respondents were males and females 18 years of age or older. The sample was a national random probability sample and the data were weighted by sex, age and region to produce nationally projectable sample proportions. All interviews were completed between March 18 and April 4, 2004. Please note the following results:

- 38% of respondents reported that carbohydrate content is a factor in food purchases. Among dieters, that number jumps to 64%. It is slightly more of a factor among women (40%) than men (35%).

- Of those who say carbohydrate content is a factor in food purchasing, "reduced-carbs" (58%) is the most attractive label followed by "net carbs" (21%). "Impact carbs" was only mentioned as a preference by 4%.
- For those interested in carbohydrate content, carbohydrate content was mentioned as a factor for purchasing bread (76%), cakes/pies/baked goods (59%), pasta (57%), cereal (53%), ice cream/frozen yogurt (54%), soft drinks (48%), and nutrition/energy/granola bars (45%).

The chemical nature of carbohydrates is not a reliable indicator of their physiological effect or their caloric value. Carbohydrates differ physiologically in that some are hydrolyzed and absorbed in the small intestine and are then metabolized (e.g., glucose, fructose, sucrose, cooked starch); some are not completely hydrolyzed and metabolized (e.g., lactose, isomalt, sorbitol, xylitol); some are absorbed, not metabolized and excreted via urine (e.g., erythritol, mannitol); some pass through the small intestine unchanged and are fermented completely or partially by gut bacteria (e.g., polydextrose, pectin, fructo-oligosaccharides, inulin, resistant starch, tagatose); and some pass through the digestive tract unchanged and are barely fermented (e.g., cellulose). The amount of the carbohydrate metabolized and absorbed is directly related to the caloric value of the carbohydrate.

Adding fiber and sugar alcohols separately from the declaration of carbohydrates in the Nutrition Facts Panel would simplify carbohydrate labeling and more effectively address recommendations of scientists and scientific groups and consumer concerns. The proposed FDA experimental study on carbohydrate labeling provides an ideal opportunity to assess consumer reaction to these requested changes in the Nutrition Facts Panel.

For example, the Institute of Medicine (IOM) report, "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids," states that adequate fiber intake for young men is 38 grams per day and for women 25 grams per day. The IOM reports median intakes of fiber ranging from 16.5 to 17.9 grams per day for men and 12.1 to 13.8 grams per day for women, noting "there is a seemingly large gap between current fiber intake and that which is recommended . . ." The IOM concludes that fiber is associated with reduced risk of coronary heart disease and "the greatest benefit comes from cereal fibers and viscous *Functional Fibers*, including gums and pectins."¹ Listing fiber separately in the Nutrition Facts Panel would call attention to product fiber content, increasing the awareness of fiber and hopefully encouraging consumers to increase their consumption of fiber. According to the Council's 2004 Survey, 57% of adult Americans agree that they "always try to check the list of ingredients."

The caloric content of food products is also important to consumers. According to the Council's 2004 Survey, 51% of those surveyed agree that they "always try to check the nutrition label for calories."

The FDA now provides, in actuality, for a caloric value of zero for insoluble fiber but requires the use of a caloric value of 4 calories per gram for soluble fiber. The IOM not only confirms the benefits of dietary fiber but also recognizes the reduced caloric value of

fiber stating, “While it is still unclear as to the energy yield of fibers in humans, current data indicate that the yield is in the range of 1.5 to 2.5 kcal/g.” Importantly, gums and pectins, described by the IOM as especially useful in the reduction of coronary heart disease risk, are soluble fibers. In 1997, the Council petitioned (Docket No. 97P-0056/CP1) the FDA for the use of a caloric value of not more than two calories per gram for soluble fiber.² The Council again urges the FDA to act on this petition as the agency addresses carbohydrate labeling in order to provide additional factual and useful information to the consumer.

The sugar alcohols or polyols³ also are reduced in calories. The FDA allows the use of the following caloric values for the polyols: 0.2 calories per gram for erythritol; 1.6 for mannitol; 2.0 for isomalt and lactitol; 2.1 for maltitol; 2.4 for xylitol; 2.6 for sorbitol; and 3.0 for hydrogenated starch hydrolysates – compared to four calories per gram generally used for carbohydrates.

Listing fiber and sugar alcohols separately in the Nutrition Facts Panel would more accurately reflect caloric content and reduce consumer confusion when trying to determine the number of calories provided by carbohydrates in the product. Clearly when the caloric value of fiber and sugar alcohols differ significantly from that of other carbohydrates, four times the number of grams of carbohydrate in the product does not equal the number of calories for carbohydrate shown in the Nutrition Facts Panel.

The Council urges the FDA to list fiber and polyols (i.e., sugar alcohols) separately and apart from the other carbohydrate⁴ content of the product in the Nutrition Facts Panel and to take the opportunity to explore consumer reaction to these suggestions in the FDA proposed experimental study on carbohydrate labeling. The Council would be pleased to provide additional data from its 2004 Survey upon request.

Respectfully submitted,

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¹The IOM also notes that polydextrose (FDA has assigned polydextrose a caloric value of one calorie per gram) and certain polyols can potentially be classified as *Functional Fiber* and classifies the naturally occurring fructans from chicory, onions and Jerusalem artichoke as *Dietary Fiber* and extracted fructans from these products as *Functional Fiber* – when sufficient data support physiological benefits.

²Other soluble fibers, for example, are agar, alginates, carrageenan, guar gum, inulin, methylcellulose, oligosaccharides, and xanthan gum.

³The FDA might consider including questions in the proposed experimental study to confirm earlier nationally projectable consumer research conducted by the Calorie Control Council and submitted to the FDA (see Docket No. 95P0099) which found that 78% of those surveyed think the term “sugar alcohol” indicates a product contains some sugar even when the product is labeled “sugar free.” Sixty-nine percent believe the product contains some alcohol.

⁴Total carbohydrate in the Nutrition Facts Panel would become Carbohydrate under this proposal.