

75 PEACHTREE-DUNWOODY RD • BLDG G, STE 500 • ATLANTA, GA 30342 • (404) 252-3663 • FAX (404) 252-0774 E-MAIL CCC@KELLENCOMPANY COM . WWW CALORIECONTROL.ORG

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November 10, 2003

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

RE: Docket No. 2003N-0338

The Calorie Control Council is an international association of manufacturers of lowcalorie and reduced-fat foods and beverages. Makers of low-calorie sweeteners, lowcalorie bulking agents and fat replacers are among the Council's members.

Enclosed are two copies of the Calorie Control Council's (the "Council") comments presented at the October 23, 2003 Public Meeting held by the U.S. Food and Drug Administration's Obesity Working Group. Specifically, the Council proposed a qualified health claim: "Using reduced-calorie [or light] foods and beverages, as part of a diet limited in fat and calories, may reduce the risk of obesity. Obesity increases the risk of developing diabetes, heart disease, and certain cancers." The Council plans to petition FDA shortly for the approval of this proposal.

The Council also wishes to bring to FDA's attention a new "online dieting site" CaloriesCount.com made possible by the calorie control food and beverage industry, through the Calorie Control Council. A number of interested food and beverage companies have provided contributions to not only make CaloriesCount.com possible but to assist in keeping the membership fees low. These sponsors are committed to helping in the fight against obesity and to the principles of healthy weight management upon which this site is based.

CaloriesCount.com, whose motto is "Healthy Eating and Exercise for Life," is dedicated to teaching and helping consumers achieve and maintain a healthy weight for life. The CaloriesCount program emphasizes the importance of losing weight gradually and adopting healthy eating and exercise habits that can be maintained long-term. This basic principle guides all the information published on the site, while dissuading consumers from looking for quick fixes. The CaloriesCount program guidelines are consistent with those of the American Medical Association, American Heart Association, American Dietetic Association, American Diabetes Association and other trusted health/medical groups, as well as the federal government (and in particular its Partners for Healthy Weight Management principles).

The need for CaloriesCount.com has become more evident as America's - and the world's - incidence of obesity has risen dramatically over recent years. It is quite clear that people need a better understanding of the importance of achieving a healthy weight and an active lifestyle, and they are striving to receive guidance about sensible, non-faddish, methods of weight control. In addition, over the past few years a number of major studies have been published in respected medical journals documenting the effectiveness of so-called "online dieting.

In sum, CaloriesCount.com offers sensible lifestyle-oriented advice supported by leading health organizations and medical professionals as well as a prestigious Scientific Advisory Board. CaloriesCount.com provides private, convenient, sensible, effective, affordable online weight management. To learn more about the site, visit, www.caloriescount.com.

Respectfully submitted,

Lyn O'Brien Nabors Executive Vice President

LON/db

**Enclosure** 

## **FDA Public Meeting on Obesity**

October 23, 2003
9:00 to 5:00 p.m.
Warren Grant Magnuson Clinical Center
Masur Auditorium (Bldg 10)
National Institutes of Health
9000 Rockville Pike
Bethesda, MD

Calorie Control Council Comments Lyn O'Brien Nabors, Executive Vice President

The Calorie Control Council is an international association of manufacturers of low-calorie and reduced-fat foods and beverages. Makers of low-calorie sweeteners, low-calorie bulking agents and fat replacers are among the Council's members. I am Lyn Nabors, Executive Vice President, of the Council. The Council is pleased to present the following comments.

Secretary Thompson, recently addressing the 2005 Dietary Guidelines Advisory Committee, noted that he comes from a state that loves milk, cheese, beer and brats and asked the Committee if they could make them have fewer calories. The good news is that such products are already available along with hundreds of other good tasting reduced calorie products.

The bad news is consumers may not be using these products appropriately. According to the Calorie Control Council's most recent consumer research on light product usage, 87% of American adults say they use light products on a regular basis – defined as at least once every two weeks. The majority of users consume these products several times per week and say they want more. However, 36% of those who say they need to lose weight admit that they often splurge on favorite full-calorie foods.

Dr. James Hill of the University of Colorado recently reported that people are gaining an extra two pounds per year or 14 to 16 pounds over an eight-year period. He notes that a simple approach to preventing this weight gain is to cut out just 100 calories per day. This "one hundred calories per day" can be cut by using reduced-calorie products in place of their full calorie counterparts. For example, simply substituting a packet of low-calorie tabletop sweetener for sugar in coffee, on cereal and in ice tea three times a day is a savings of about 100 calories. Consuming eight ounces of a "light" yogurt sweetened with low calorie sweeteners in place of a low-fat yogurt saves about 140 calories, choosing a cup of skim milk in place of whole milk saves 60 calories, substituting a serving of sugar-free gelatin dessert for its traditional counterpart saves 70 calories, using

fat free potato chips in place of regular chips saves 75 calories per ounce, replacing a regular soda with a can of diet soda saves 150 calories, and the list goes on and on.

It is a well known that weight loss is the result of expending more calories than consumed. Additional calories would, therefore, need to be cut from the diet or activity increased – and preferably both – in order to lose weight.

Low-calorie sweeteners and the products containing them provide sweetness and "good taste" without the calories of their full calorie counterparts. Research demonstrates that when sucrose is covertly replaced with low-calorie sweeteners non-dieting obese and normal weight individuals incompletely compensate for the calorie reduction. In other words, they consume fewer calories.

Importantly, a 3-year scientific study conducted at Harvard Medical School showed that the low-calorie sweetener, aspartame, was a valuable aid to a long-term weight management program that included diet and physical activity.

And, a recent study to determine the impact of reduced calorie foods and beverages (i.e., products sweetened with low-calorie sweeteners) was undertaken to determine the quality of the diets of American adults. The micronutrient quality of the diet of those using reduced-calorie products was significantly better than those who did not use such products and energy intake was reduced.

Clearly, there are significant benefits when products reduced in calories are incorporated into a sensible diet. Today, the Council proposes labeling that would make low calorie foods more attractive to consumers and allow food and beverage manufacturers to more favorably position their products. The proposed labeling would also assist in educating consumers about the risks of obesity and the important role reduced-calorie products can play.

Thus, please consider for approval the following: "Using reduced-calorie [or light] foods and beverages, as part of a diet limited in fat and calories, may reduce the risk of obesity. Obesity increases the risk of developing diabetes, heart disease, and certain cancers."

We trust the FDA will give serious consideration to this proposed qualified health claim and the Council will formally propose such labeling to the agency with additional supporting data shortly.

Thank you.

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