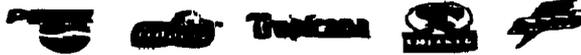


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FDA

**PEPSICO****VIA OVERNIGHT MAIL**

December 19, 2003

Robert E. Brackett, Ph.D.
Director of Food Safety and Security Staff
CFSAN, FDA
HPS-32, Room 3B004
5100 Paint Branch Parkway
College Park, MD 20740

Re: Allowance For "Reduced" Carbohydrate Claims

Dear Dr. Brackett:

There is a widening gap between consumer interest in carbohydrate intake and the ability of food companies to communicate this information on the food label. To maintain the orderly flow of truthful, nonmisleading information to consumers via the food label, PepsiCo Inc, which today includes not only the carbonated beverages that consumers most often associate with the Pepsi name, but also Aquafina® waters, Frito-Lay® snacks, Tropicana® Pure Premium® Juices, Gatorade® and Propel® fitness drinks and Quaker® wholegrain and oat-based products, urges the Food and Drug Administration to take immediate steps in exercise of its enforcement discretion to allow for "reduced carbohydrates" claims for qualifying products.

Because "reduced carbohydrates" is a nutrient content claim not currently authorized by regulation, a product bearing such claim is misbranded pursuant to Section 403(r)(1) of the Federal Food, Drug, and Cosmetic Act. FDA has issued several Warning Letters affirming this prohibition. Owing, we suspect, to the lack of interest in carbohydrate content when the current rules were written in 1993, carbohydrate content claims have never been defined. Presently, carbohydrate content information

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is permitted if presented in terms of the quantitative amount or percentage (of the DV) of the nutrient in a food, in the form of dietary guidance, or otherwise in a fashion that does not characterize the level of carbohydrates in a particular food.

Consumer interest in carbohydrate intake is immediate and growing substantially. While various consumer surveys may rank order the importance of calories, carbohydrates and fat differently, they are key nutrients of importance to consumers. A PepsiCo Attitude and Usage study in May of 2003 found 55 percent of consumers were concerned about and are reducing their carbohydrates. The top three reasons consumers gave for reducing their carbohydrates were: to lose weight; for overall health; and because carbohydrates are fattening. In a separate survey, carbohydrates and fat were key nutrients dieters limit in their diet with 42 percent of dieters limiting carbohydrates and 24 percent limiting fat. A study conducted in 2002 found that when asked about the importance of claims on labels, "good source of calcium" topped the list with 46 percent finding it very or extremely important. "Low fat," "low calorie," or "low carbohydrate" were important or extremely important claims to 39 percent, 35 percent and 26 percent respectively. These studies demonstrate that there is substantial consumer interest in carbohydrate intake and this interest is growing.

A "reduced carbohydrates" claim that highlights a food that contains at least a 25 percent reduction in carbohydrate compared to an identified and appropriate reference food would provide valuable, truthful, and nonmisleading information to consumers. Existing regulations that define "carbohydrate" and provide general principles for presentation of relative claims would ensure that such information can be provided in a uniform, factual fashion. Unlike the complexity FDA may face in defining "low carbohydrates," a "reduced carbohydrates" claim is straightforward. While PepsiCo will continue to work with its trade associations in developing a petition or other information that would define by regulation a wider universe of carbohydrate-related claims, we believe that a "reduced carbohydrates" claim can be sanctioned with little or no delay.

Statements concerning the amount and percentage of nutrients in food are authorized under the existing regulations. The agency acknowledges that these statements are generally useful to consumers in pointing out the level of a nutrient in the food, identifying foods that facilitate conformance to

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current dietary guidelines, and facilitating comparisons between foods. (58 Fed. Reg. 2302, 2310 (1993)). These same objectives would be advanced by a "reduced carbohydrates" claim, which merely highlights foods of particular interest to consumers who limit their carbohydrate intake.

Authorization of a "reduced carbohydrates" claim in accordance with the above-described parameters would be fully consistent with the manner in which FDA has defined "reduced" for other nutrients. FDA has consistently held that "twenty-five percent represents the extent of reduction necessary to make a 'less' or 'reduced' claim for a variety of regulated nutrient claims." (*Id.* at 2341). The agency has stated that the terms "less" and "reduced" should only be used when a nutritionally significant reduction in the level of the nutrient has been reached so consumers would not be confused or led to believe that a product would provide a nutritionally significant reduction in the level of a nutrient when it would not. (*Id.* at 2348). FDA has uniformly concluded that a 25 percent reduction is appropriate for foods designated as "reduced" in calories, sugar, sodium, fat, saturated fat and cholesterol.

FDA should take appropriate steps to allow for the immediate use of "reduced carbohydrates" claims in accordance with the 25 percent reduction requirement it has applied without exception in the past. Initially, the agency could issue a policy articulating the exercise of its enforcement discretion for use of "reduced carbohydrates" claims. The agency could then move to rulemaking and publish an interim final rule that would allow for use of the claim and a comment period. Nutrition health policy has yet to fully investigate or reach a consensus as to the role of carbohydrate intake. These open questions do not provide a basis for prohibiting companies from highlighting products that contain significantly less carbohydrate than a reference food.

This request advances a fundamental purpose of the food label - - providing nutrition-related information that facilitates informed purchasing decisions. FDA leadership in taking interim measures to allow for "reduced carbohydrates" claims is central to the agency's ability to maintain regulatory oversight in a marketplace that has witnessed an explosion of interest among consumers in carbohydrate content, and strong industry response. The proposed action also allows for factual statements about the reduction in carbohydrate content in a fashion consistent with the protections afforded commercial speech by the First Amendment.

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We welcome the opportunity to provide additional information or to discuss the need for swift action on "reduced carbohydrates" claims. Thank you for your consideration of this request.

Sincerely,



Nancy R. Green, Ph. D
Vice President Nutrition Technology
PepsiCo Wellward Institute of Nutrition



Mark L. McGowan
Chief-Counsel
Foods Division
Pepsi Beverages and Foods

cc: Mark B. McClellan, M.D., Ph.D.
Kathleen Ellwood ✓