

January 7, 2003

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

Re: [Docket No. 02P-0462] Food Labeling: Nutrient Content Claims; Implied
Nutrient Content Claim in the Brand Name CARBOLITE
67 Federal Register 72963, December 9, 2002

Dear Sir or Madam:

General Mills is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. General Mills is a major packaged-food manufacturer engaged for over 60 years in the development and production of food products including flour, ready-eat-cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

We have been committed to nutrition labeling for over 25 years beginning with voluntary labeling in 1974. We currently have nutrition labeling on more than 1500 retail products. Over the years, we have added additional information and claims to our products in response to consumer interest in newer knowledge about the relationship of diet and health. General Mills firmly supports changes in food-labeling practices that will provide consumers with nutrition information more relevant to today's needs.

We appreciate the opportunity to comment on the concepts and claims proposed in the Carbolite Foods® Petition submitted to the Agency.

As a food manufacturer of carbohydrate-based foods such as cereals, breads, ready to bake breads and rolls, grain-based entrées and snacks, we are opposed to the approval of the Carbolite Foods® *Petition for the Use of an Implied Nutrient Content Claim in the Brand name Carbolite®* for two reasons.

We believe:

~~✍✍~~**The term *Carbolite* and *net effect carbs* used in this context are misleading and confusing to health professionals and consumers.**

~~✍✍~~**That allowing the exclusive use of carbohydrate terms by a single company is unfair. Since the FDA currently prohibits the use of expressed carbohydrate claims, if carbohydrate-related terms are to be allowed, they should be subject to normal rule making procedure.**

The terms *carbolite* and *net effect carbs* are misleading

Carbolite Foods® states that they are marketing a line of “zero sugar” or “reduced sugar” products designed to limit the overall intake of carbohydrates having a noted effect on blood sugar (i.e. “*net effect carbs*”). Their claim is that by reducing these sugars and replacing them with sugar alcohol sweeteners, there will be no notable effect on blood levels or insulin and as a result, these products can be incorporated into low carbohydrate diets ultimately achieving weight loss. (This is based on the premise of Dr. Atkins’ and other low carbohydrate diets that “Low carbohydrate diets achieve weight loss through metabolic processes that are produced naturally in the body when the dietary intake of *net effect carbs* is restricted below certain threshold levels”).

We believe there are several issues with this proposal that make it misleading. One, this premise is not supported by research. Two, the name *Carbolite* and

the *net effect carbs* claims imply that these products are lower or “light/lite” in carbohydrate; but they are **only** lower in sugar, not total carbohydrate. Finally, these claims seem to be based on the premise that it is a metabolic effect that causes this reduction. There is no precedent for defining low or light/lite nutrient claims based on a metabolic effect. These are nutrient content claims and should be based on comparative levels of existing products and as such, claims for “lite carbohydrate” or “low carbohydrate” should meet the requirements for “low” or “light” nutrient content claims. If these claims are based on metabolic effect, then we believe these should be positioned as structure/function or health claims with supporting research. We are not aware of clinical research that would support such claims. The petition states “FDA’s policy does not account for the connection between sugar restriction and weight loss that depends on controlling blood sugar levels rather than calories”. This is undoubtedly because there is no scientific evidence to support this claim.

Carbolite® Foods argues that implied claims in brand names are subject to a more liberal interpretation than express nutrient content claims. They argue that the statutory standard requires FDA to approve petitions for the use of implied claims in brand names where the conditions of approval harmonize-and do not conflict conceptually- with the existing body of regulations. In this case, however, we believe these claims do not meet these requirements and are misleading to the consumer for the reasons stated above.

While we support the concept of providing the consumer with a choice of products that are lower in sugar, Carbolite® Foods do not meet the defined terms for *light/lite* or for *carbohydrate* and therefore are misleading and offer a disservice to the consumer as well as the health professionals attempting to counsel patients on healthy weight management.

Allowing exclusive of use of carbohydrate claims is unfair to the other manufacturers of carbohydrate-containing foods.

Currently, FDA does not allow low carbohydrate, light carbohydrate or similar claims about carbohydrate to be made. If claims regarding carbohydrate are to be allowed, they should be proposed in the normal rulemaking process giving all interested an opportunity to comment. Allowing the use of the term “carbomite” in the present context would apparently prohibit other companies from using a light/low carbohydrate claim without petitioning the FDA. This would be unfair to the food industry as well as to the consumer to allow exclusive right to the use of these terms and to allow it in a misleading context.

Respectfully submitted,

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