

A

Carbolite Foods, Inc.
1325 Newton Avenue
Evansville, IN 47715



Phone: 800 524-4473
Fax: 812 485-0002
www.carbolitedirect.com

October 25, 2004

Petitioner: Carbolite Foods, Inc.

Address: 1325 Newton Avenue
Evansville, IN 47715

Subject of the Petition: Labeling Claims Using "Net Effective Carbohydrates" and Similar Terms

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

CITIZEN PETITION

Carbolite Foods, Inc. ("Carbolite") submits this Citizen Petition under sections 201(n) and 403(a) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and section 2(c) of the Nutrition Labeling and Education Act of 1990 ("NLEA") (104 Stat. 2353, 2357), and in accordance with the First Amendment and the requirements established in 21 C.F.R. § 10.30, to request the Commissioner of Food and Drugs ("FDA") to issue food labeling and enforcement policy guidance accepting the term "net effective carbohydrate" and similar terms for use in food labeling to represent the net amount of carbohydrates calculated by subtracting the amounts of "dietary fiber" and "sugar alcohols" from the amount of "total carbohydrates" declared in the Nutrition Facts box.

Carbolite produces alternative food products which have been specially formulated for consumers adopting dietary weight loss regimens that restrict the intake of certain carbohydrates ("low carbohydrate" or "low carb" regimens). The product lines produced by Carbolite include a diverse variety of alternative candies, snack bars, beverage, shake and bakery product mixes. Carbolite was one of the first producers of alternative candies formulated for use in "low carbohydrate" weight loss regimens. The company now offers an extensive line of such alternative food products, which are distributed internationally. As an industry leader, Carbolite understands the critical need of consumers to receive accurate, substantiated and meaningful

information in food labeling that distinguishes the carbohydrate components of food that are typically restricted in "low carbohydrate" regimens from other carbohydrates for which consumption is encouraged (e.g., dietary fiber).

A. Action Requested

Carbolite requests FDA to issue food labeling and enforcement policy guidance affirming the agency's commitment to promote consumer education concerning the carbohydrate components of food that are commonly restricted in "low carbohydrate" weight loss regimens; and to secure First Amendment protections of accurate, substantiated carbohydrate information, including by recognizing that the term "net effective carbohydrate" and similar terms may be used in food labeling to represent the amount of carbohydrates calculated by subtracting the amounts of "dietary fiber" and "sugar alcohols" from the amount of "total carbohydrates" declared in the Nutrition Facts box. Carbolite proposes that such FDA guidance include the following provisions:

"Human dietary habits are diverse, evolving, and are shaped by social and cultural factors, as well as individual needs and values that affect personal food, health and lifestyle choices. These complex dynamics influence consumer preferences concerning weight loss dietary regimens, including consumer choices to adopt regimens restricting the intake of certain carbohydrates in the total daily diet (e.g., "low carbohydrate" regimens).

Weight loss dietary regimens that accommodate the individual needs and values of consumers may promote sustained dietary compliance and successful weight loss. Healthy weight loss regimens may vary significantly with respect to the levels of sugars, starches, and other carbohydrates consumed in the total daily diet. For example, regimens preferred by vegetarian consumers may include substantial amounts of grains, legumes, fruits, vegetables, and other plant-derived foods supplying significant amounts of sugars, starches, and other carbohydrates to the total diet. In contrast, regimens preferred by other consumers may include substantial amounts of animal-derived foods, including dairy products, meat, poultry, and egg products, foods that may supply relatively smaller amounts of sugars, starches, and other carbohydrates to the total diet. For consumers adopting "low carbohydrate" regimens, dietary preferences may limit the intake of foods supplying significant amounts of restricted carbohydrates (e.g., sugars and starches).

Consumers adopting "low carbohydrate" regimens may benefit from food labeling information characterizing the carbohydrate components of food to distinguish carbohydrates that are restricted from those that are excluded from dietary restrictions. The net

amount of restricted carbohydrate can reasonably be calculated from required nutrition labeling by subtracting the amounts of dietary fiber and sugar alcohols declared from the amount of total carbohydrate declared in the Nutrition Facts box required for a particular food product. Such terms as "net effective [carbohydrates/carbs]," and "net impact [carbohydrates/carbs]," are commonly used in food labeling to represent the net amount of restricted carbohydrates calculated in this manner and to make comparisons between alternative and traditional foods. (Examples: "X grams net effective carbohydrates = (X grams total carbohydrate) minus (X grams sugar alcohol) minus (X g dietary fiber)"; "Net effective carbohydrates reduced by 75% compared to [reference food].")

Existing FDA food labeling policy authorizes accurate, substantiated claims that characterize food and food components in a manner intended to assist consumers in making personal food choices in accordance with their individual needs and values. See 21 C.F.R. § 101.65(b)(1) (authorizing claims characterizing particular food components to assist consumers in avoiding consumption); 21 C.F.R. § 101.65(b)(3) (authorizing claims characterizing particular food components to assist consumers in selecting foods consistent with personal values). FDA policy distinguishes such claims from "nutrient content claims," which are subject to FDA regulations established in support of national public health objectives concerning diet and health matters. Where claims characterizing the carbohydrate components of food are intended to assist consumers in avoiding excess consumption of restricted carbohydrate components in "low carbohydrate" weight loss regimens, such claims are excluded from regulation as nutrient content claims under sections 101.65(b). Such claims must be accurate and substantiated in accordance with sections 403(a) and 201(n) of the Federal Food, Drug, and Cosmetic Act.

B. Statement of Grounds

Approximately 26 million Americans currently are following carbohydrate-restricted regimens such as the "low carbohydrate" weight loss regimens outlined in the bestselling books, "Dr. Atkins New Diet Revolution" and Dr. Arthur Agatston's "South Beach Diet." See Daniel Kadlec, "The Low-Carb Frenzy," *Time*, May 3, 2004, at 48. These regimens restrict the amount of carbohydrate that may be consumed in the total daily diet, but typically exclude from restriction carbohydrates consumed in the forms of dietary fiber and sugar alcohols. The net amount of carbohydrates that are subject to these dietary restrictions can be calculated from the nutrition labeling information required under FDA rules, by subtracting the amounts of dietary fiber and sugar alcohols declared from the amount of total carbohydrate

declared in the Nutrition Facts box. The resulting calculated net carbohydrate value reasonably represents the amount of restricted carbohydrate in the food, and represents principally the sugar and starch components of the food.

The net amount of restricted carbohydrate in a food is commonly termed "net effective carbohydrate," "net impact carbohydrate," "net carbohydrate," and similar terms in the context of "low carbohydrate" weight loss regimens. Food manufacturers formulating products for use in these regimens commonly employ these terms in informative food labeling to assist consumers in identifying products that conform with their special dietary needs. Carbolite urges FDA to issue the food labeling and enforcement policy guidance proposed here to ensure that consumers adopting "low carbohydrate" weight loss regimens receive the carbohydrate information they want and need to satisfy their special dietary needs.

1. Claims Concerning Individual Dietary Needs and Values

Existing FDA policy authorizes the use of accurate, substantiated food labeling claims that characterize food and food components in a manner intended to assist consumers in making food choices that are consistent with their personal needs and values. Under FDA regulations, such claims are excluded from regulations governing "nutrient content claims." See 21 C.F.R. § 101.65(b)(1) (authorizing claims characterizing food components to assist consumers in avoiding consumption); 21 C.F.R. § 101.65(b)(3) (authorizing claims characterizing food components to assist consumers in selecting foods in accordance with personal values).

FDA regulations define "nutrient content claims" to mean claims that "expressly or implicitly characterize[] the level of a nutrient of the type required to be in nutrition labeling" 21 C.F.R. § 101.13(b). Implied nutrient content claims may include statements describing "a food or ingredient" when the statement "suggests that a nutrient is absent or present in a certain amount (e.g., 'high in oat bran')." 21 C.F.R. §§ 101.13(b)(2)(i), 101.65(c). Implied nutrient content claims may also include claims "denoting foods that are useful in constructing a diet that is consistent with dietary recommendations" (e.g., "healthy, contains 3 grams (g) of fat"). 21 C.F.R. §§ 101.65(d)(2), 101.13(b)(2)(ii).

In distinguishing nutrient content claims from other claims characterizing the nutritional components of food, FDA has stressed the general public health purposes of the nutrient content claims regulations to implement the dietary guidelines addressing diet and health matters for the general population. In the preamble to the final regulations, FDA emphasized, "[t]hese [nutrient content claim] regulations are intended to define nutrient content claims for categories of nutrients or individual nutrients that are required for maintaining a diet that meets current dietary guidelines (e.g., fiber, cholesterol, and fat)." 58 Fed. Reg. 2302, 2400 (January 6, 1993). The agency has been clear in distinguishing the regulatory policy objectives for claims addressing the special dietary needs and values of individual consumers from the more general public health objectives established for nutrient content claims. 58 Fed. Reg. at 2370 (claims intended to assist consumers adopting special weight loss dietary regimens are not considered nutrient content claims). Notably, FDA regulations define "special dietary uses" to mean "particular (as distinguished from general) uses of food," which may include foods used to

address "particular dietary needs" including with respect to "overweight" and "regulation of the intake of ... available carbohydrate." 21 C.F.R. §§ 105.3(a)(1)(i), (a)(2).

Accordingly, while FDA has defined nutrient content claims concerning certain carbohydrates considered to have general public health importance under the dietary guidelines, including "sugars" and "dietary fiber," the agency has declined to establish nutrient content claims for other carbohydrates important to consumers adopting special dietary practices. For example, in declining to regulate claims characterizing the lactose content of food as nutrient content claims, FDA explained, "[l]actose, a sugar that occurs in milk, is not a nutrient addressed in current dietary guidelines. However, labeling in regard to the lactose content of food does have significance for individuals who cannot tolerate this nutrient." 58 Fed. Reg. at 2400-2401.

More generally, section 101.65(b)(1) of FDA regulations codifies a general exclusion from nutrient content claim regulation for claims characterizing particular food components to assist consumers who have adopted special dietary practices in accordance with individual needs or values. "Statements that declare the absence of other food components or ingredients that are not nutrients of the type required to be declared in nutrition labeling and that are intended to facilitate avoidance of the substance for such reasons as food intolerance, religious beliefs, or dietary practices (such as vegetarianism), e.g., '100 percent milk-free,' are [] not nutrient content claims." 58 Fed. Reg. at 2369. Similarly, section 101.65(b)(3) of FDA regulations codifies an exclusion from nutrient content claim regulations for claims characterizing food components perceived by certain consumers to have particular value. 58 Fed. Reg. at 2369 (stating that such "claims would be useful as tools for the manufacturer to communicate to the consumer that the product is of high quality because premium or otherwise preferred ingredients have been used."). Such claims could characterize valuable components of foods formulated for use in special dietary regimens, such as "low carbohydrate" regimens (e.g., sugar alcohols).

2. "Net Effective Carbohydrate" and Similar Claims

Manufacturers have responded to consumers following "low carbohydrate" weight loss regimens by providing accurate, substantiated information in food labeling that distinguishes the amount of total carbohydrate declared in the Nutrition Facts box from the amount of carbohydrate that typically is subject to the dietary restrictions applied in such weight loss regimens. Manufacturers have adopted such terms as "net effective carbohydrates," "net impact carbohydrates," and "noneffective carbohydrates" to represent the net amount of restricted carbohydrates calculated from nutrition labeling information when the grams of sugar alcohol and dietary fiber are subtracted from the grams of total carbohydrate declared in the Nutrition Facts box.

The carbohydrates represented by the "net effective carbohydrate" term and similar terms consist principally of the sugar and starch components of food. These carbohydrates constitute a subcategory of "total carbohydrates" that FDA has represented as "fermentable carbohydrate," for certain food labeling purposes. See 21 C.F.R. § 101.80(a)(2), (d). As in the case of lactose, "fermentable carbohydrate" provides nutritional value, but does not itself constitute a "nutrient" addressed in dietary guidelines established for the general

population. Labeling that characterizes the "net effective carbohydrate" content of food has significance for consumers choosing to adopt particular "low carbohydrate" weight loss regimens in which excess intake of these carbohydrates is avoided.

The FDA food labeling and enforcement policy guidance proposed here would recognize that "net effective carbohydrate" and similar claims characterizing the carbohydrate components of food are properly excluded from nutrient content claim regulation on grounds analogous to those FDA established for lactose content claims¹ under 21 C.F.R. § 101.65(b)(1) (and 21 C.F.R. § 105.62), and constitute a reasonable representation of the amount of restricted carbohydrates in food.

The proposed food labeling and enforcement policy guidance is consistent with the "Statement of Interim Policy on Carbohydrate Labeling Statements" issued by the USDA Food Safety and Inspection Service (FSIS) on December 22, 2003. (Available at <http://www.fsis.usda.gov/OPPDE/LARC/POLICIES/CARBLABEL.htm>) Under the FSIS policy, accurate, substantiated terms representing the amount of restricted carbohydrates in food, including "Net Carbs," "Net Effective Carbs," and "Net Impact Carbs," are permitted. *Id.* The FSIS policy provides that such terms "must be accompanied by specific information informing the consumer of the meaning of the use of such terms on labeling and providing the calculation necessary to determine the number of carbohydrates included by the term." *Id.*

The proposed guidance is also consistent with the dictates of the First Amendment, which places a heavy burden of proof on FDA before it can restrict manufacturers' use of specific terms in food labeling. Under the First Amendment, the government lacks legal authority to place any restriction on commercial speech except where it proves, based on evidence, that the restriction is necessary to remedy a concrete harm presented by the specific speech at issue. The government may not ban accurate, substantiated claims.² Thus, as a threshold matter, a regulatory scheme that allows only preapproved label claims in particular iterations will be highly suspect, for the First Amendment favors a case-by-case approach that

¹ FDA expressly refused to regulate "free," "low," and "reduced" claims for lactose as nutrient content claims. 58 Fed. Reg. 2302, 2400-01 (Jan. 6, 1993). "Lactose-free" and "[X] % lactose-reduced" claims are commonly used in the marketplace on products geared towards consumers seeking to reduce or eliminate lactose intake. Comparable claims characterizing the "net effective carbohydrate" components of food products should likewise be recognized, where the claims are intended to assist consumers seeking to limit their intake of the carbohydrates restricted in "low carbohydrate" regimens.

² Where FDA concludes that the arithmetic calculation of "net effective carbohydrates" coupled with a disclosure of the nature of the calculation, as we propose, provides insufficient information to meet the needs of a subpopulation with special medical needs, FDA should not ban the proposed "net effective carbohydrate" statement. Rather, the agency should promote "more speech" in accordance with First Amendment standards.

permits analysis of the particular harm to be addressed by the speech restriction in every instance, such as that conducted through adjudication or enforcement.³

3. Food and Nutrition Policy Considerations

Accurate, substantiated "net effective carbohydrate" claims promote healthy dietary practices for those consumers adopting "low carbohydrate" regimens by encouraging adequate dietary fiber intake, while assisting consumers in avoiding excess intake of sugars and other restricted carbohydrates. Consumers following "low carbohydrate" weight loss dietary regimens seek to consume nutritious foods that can be integrated readily into the overall diet in a manner that avoids excess consumption of restricted carbohydrate components of food. Such consumers may prefer to consume foods sweetened with sugar alcohols to assist them in avoiding added sugars, and making room in the diet for nutritious foods containing restricted carbohydrates (e.g., fruits, vegetables, grain products). In addition, while dietary fiber intake is not restricted, these consumers may find it challenging to consume dietary fiber in the amounts that are recommended by dietary guidelines for the general population, and may benefit from high fiber foods that are specially formulated to reduce the levels of sugars and starches compared to traditional product formulations. Notably, the recently-issued 2005 Dietary Guidelines Advisory Committee Report recommends that Americans "choose carbohydrates wisely for good health," and urges that Americans modify their current dietary intake by increasing intake of dietary fiber and reducing intake of added sugars to promote weight control and nutrient intakes at recommended levels. *See, e.g.*, "Backgrounder, 2005 Dietary Guidelines Advisory Committee Report," available at <http://www.health.gov/dietaryguidelines/dga2005/Backgrounder.htm>.

There is ample regulatory precedent supporting the use of "net effective carbohydrates," "net impact carbohydrates," and similar terms in food labeling to represent the amount of restricted carbohydrates in food where the labeling includes accurate, substantiated information explaining the meaning of the specific term that is used and distinguishes the amounts of unrestricted carbohydrates in the food which constitute sugar alcohols and/or dietary fiber. Such claims are consistent with existing FDA policy and promote healthy dietary practices among consumers adopting "low carbohydrate" weight loss dietary regimens. In contrast to food labeling approaches which would focus on characterizing the level of total carbohydrate in food, Carbolite's proposed food labeling and enforcement guidance provides strong support for general public health recommendations concerning dietary fiber intake.

C. Environmental Impact

The action requested by this Citizen's Petition is not expected to have a significant effect on the quality of the human environment, and is subject to categorical

³ See Carbolite's discussion of the serious First Amendment concerns implicated by a premarket clearance approach to label claims in Carbolite's comments filed today under Docket Nos. 1994P-0390 and 1995P-0241, a copy of which is attached to this petition as Attachment A.

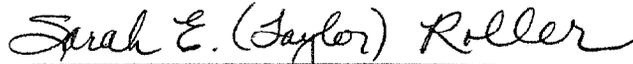
exclusion under 21 C.F.R. § 25.30(h). To the best of Petitioner's knowledge, no extraordinary circumstances exist that would require an environmental assessment under 21 C.F.R. § 25.21.

D. Certification

The undersigned certifies that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,


Gerry Morrison
President
CARBOLITE FOODS, INC.
1325 Newton Avenue
Evansville, IN 47715
Tel: (800) 524-4473
Fax: (812) 485-0006
gmorrison@carbolite.com


Sarah E. (Taylor) Roller, J.D., R.D., M.P.H.
Miriam Guggenheim, Esq.
COVINGTON & BURLING
1201 Pennsylvania Ave., NW
Washington, DC 20004
Tel: (202) 662-6000
Fax: (202) 662-6291
sroller@cov.com
mguggenheim@cov.com

*Counsel to the Petitioner,
Carbolite® Foods, Inc.*