

Chocolate Manufacturers Association • National Confectioners Association

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

Re: Docket No. 02P-0462

Dear Sir or Madam:

The Chocolate Manufacturers Association (CMA) and the National Confectioners Association (NCA) appreciate this opportunity to comment on the petition by Carbolite® Foods, Inc. to use an implied nutrient content claim in its brand name. CMA and NCA strongly oppose this petition and urge the Food and Drug Administration (FDA) to deny it.

CMA is the national not-for-profit association representing the majority of chocolate manufacturers in the United States. CMA members produce over 90 percent of all chocolate manufactured in this country. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture and market a wide variety of finished chocolate and chocolate-containing products for the consumer market. NCA is the national not-for-profit association representing more than 650 confectionery manufacturers and suppliers.

CMA and NCA believe that “Carbolite” does not meet the statutory criteria for approval of an implied nutrient content claim in a brand name. We believe there is a fundamental disconnect between the proposed nutrient content claim, “Carbolite,” and the nutritional criteria proposed for allowance of the claim, “zero sugar” or “reduced sugar.” Finally, we believe it would be bad public policy for FDA to alter its long-standing policy, which does not allow nutrient content claims about a food’s total carbohydrate content.

1. “Carbolite” Does Not Satisfy the Statutory Criteria for an Implied Nutrient Content Claim in a Brand Name.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA must grant a petition for permission to use an implied nutrient content claim in a brand name if FDA finds that such claim is:

(i) not misleading, and (ii) consistent with the nutrient content claims defined in FDA regulations. 21 U.S.C. § 343(r)(4)(A)(iii). The nutrient content claim “Carbolite” proposed by this petition meets neither of the two statutory criteria for approval. It is clearly inconsistent with existing defined nutrient content claims, and it is inherently misleading to consumers.

a. “Carbolite” is Inconsistent with FDA’s Defined Nutrient Content Claims.

Despite the petitioner’s logical contortions, the proposed nutrient content claim “Carbolite” is plainly not consistent with existing FDA defined nutrient content claims. While the term “Carbolite” is a novel term, its meaning is clear. “Carbolite” means that a food is low in total carbohydrates. A “low in total carbohydrates” nutrient content claim is clearly inconsistent with existing nutrient content claim regulations.

As the petitioner notes, FDA specifically declined to authorize any nutrient content claims for total carbohydrates.¹ In fact, the petition admits, in so many words, that “Carbolite” is not consistent with the existing regulatory scheme for nutrient content claims. According to the petitioner, “while current FDA policy recognizes that ‘fermentable carbohydrates’ (*i.e., net effective carbs*) constitute a class of carbohydrates that are metabolically distinguishable from other carbohydrates..., this distinction, which is important for low carbohydrate diets, is not reflected in FDA policy defining carbohydrates for purposes of nutrient content claims or nutrition labeling.”²

Petitioner next argues that the lack of a regulation authorizing nutrient content claims for total carbohydrates was an oversight due to the fact that FDA was unaware of the benefits of low-carb diets when it issued its regulations.³ This argument is both incorrect and beside the point. If the

¹ FDA specifically excluded total carbohydrates from “good source,” “high,” “more,” and “high potency” nutrient content claims. 21 C.F.R. § 101.54(a). While authorizing nutrient content claims for calorie and sugars content, FDA did not authorize any claims for total carbohydrates. 21 C.F.R. § 101.60.

² Carbolite® Foods, Inc., Petition for the Use of an Implied Nutrient Content Claim in the Brand Name “Carbolite®”, October 4, 2002 (Petition), at 11 (emphasis added).

³ According to the petition, “[t]he current FDA policy which authorizes no expressed nutrient content claims for ‘carbohydrate’ is reflective of the policy priorities during the period the relevant statutory provisions were implemented.... During that time, agency policy objectives emphasized the promotion of low fat diets.... Only a limited range of issues were considered with respect to carbohydrate consumption.... At no time did FDA consider the food labeling issues presented by the low carbohydrate diets that are popular now....” Petition, at 11.

petitioner believes there should be nutrient content claims for total carbohydrates, the petitioner should submit a petition to amend the nutrient content claim regulations. The instant petition requires a showing that the proposed nutrient content claim is consistent with existing defined nutrient content claims, and it clearly is not.

The argument that FDA was unaware of the benefits of low-carbohydrate diets when it refused to allow nutrient content claims for total carbohydrates is also mistaken. FDA considered and correctly rejected such claims at the time.⁴ FDA refused to authorize nutrient content claims for total carbohydrates, because, then as now, there was no convincing public health justification for such claims:

Dietary recommendations generally encourage the increased consumption of complex carbohydrates, while suggesting that sugars intake be limited. Therefore, a nutrient content claim such as 'high in carbohydrate' or 'source of carbohydrate' provides misleading dietary advice. At best, the claim is misleading in that it does not allow for the distinction between high levels of complex carbohydrates and high levels of sugars.

56 Fed. Reg. 60421, 60444 (Nov. 27, 1991). The same is true today. Dietary recommendations generally encourage increased consumption of some carbohydrates (*e.g.*, whole grains) and decreased consumption of others (*e.g.*, sugars).⁵

b. The Proposed “Carbolite” Claim Is Misleading.

CMA and NCA believe that the “Carbolite” claim is inherently misleading. There is an obvious disconnect between the claim, which implies that the labeled food is low in total carbohydrates, and the proposed criteria for its use, which pertain only to the labeled foods’ sugars content.

⁴ It is worth noting that low-carb diets, such as the Atkins Diet, were in existence in 1993, even if they had not yet achieved their current popularity.

⁵ See, *e.g.*, U.S. Department of Agriculture, Department of Health and Human Services, *Nutrition and Your Health: Dietary Guidelines for Americans 2000* (“Eating plenty of whole grains.... may help protect you against many chronic diseases.”); Hu, FB and WC Willett, Optimal diets for prevention of coronary heart disease. *JAMA*. 2002;288: 2569-2578, 2573 (“.... Carbohydrate-containing foods should not be judged simply by their GI [glycemic index] values; the amount of carbohydrates, fiber, and other nutrients are also important.”).

The petitioner claims that any potential for the claim to mislead consumers can be corrected by means of qualifying statements or disclaimers. For example, any potential for the suffix “lite” to mislead consumers into believing that the labeled product is low in fat or calories can be avoided by means of a disclaimer stating that the food is “not necessarily ‘light’ or ‘low’ in calories or fat.”

The petition does not explain, however, how the proposed disclosures will prevent consumers from being misled into believing that the labeled product is low in total carbohydrates. As the petition acknowledges, the prefix “carbo” in “Carbolite” is a reference to “carbohydrate.” In the absence of any qualifier (*e.g.*, “*other carbohydrate*,” “*complex carbohydrate*”), “carbo” refers to total carbohydrates. Most consumers are likely to interpret the brand name “Carbolite” to mean that the product is low in total carbohydrates. Yet, petitioner’s products are not “low in total carbohydrates” under any reasonable definition of that term. According to the label proofs attached to the petition, Carbolite® bars contain 25 to 27 grams of total carbohydrates per serving. Under the terms of the petition, however, a food that is “sugar free” or “reduced sugar” but has substantial amounts of other carbohydrates (*e.g.*, sugar alcohols, fiber) could nevertheless be labeled “Carbolite.”⁶

The petition argues that “Carbolite” will be understood by consumers to mean that the labeled product is appropriate for individuals on low-carbohydrate weight loss diets. However, the petition offers no evidence to support this assumption, and the petitioner’s assurance cannot overcome the plain meaning of the words used in its brand name. It should also be noted that Carbolite® products are not marketed in specialty stores or only to individuals on weight loss diets; they are marketed to the general public in Wal-Mart and similar stores.

2. The Petitioner’s First and Fifth Amendment Arguments Are Without Merit.

The petitioner’s constitutional arguments are unpersuasive. The U.S. Supreme Court has enunciated a four-part test for determining whether government regulation of commercial speech is consistent with the First Amendment. Under that test, in order to enjoy First Amendment protection, commercial speech must concern lawful activity and may not be misleading. *Central Hudson Gas & Electric Corp. v. Public Service Com’n of New York*, 447 U.S. 557, 561 (1980). As discussed above, the proposed “Carbolite” claim is inherently misleading and, therefore, not protected by the First Amendment at all.

⁶ The potential for confusion is enhanced by petitioner’s proposed use of the term “zero sugar carbs” (or “0 sugar carbs”) on its labels.

The petitioner's Fifth Amendment argument, because it is dependent on its First Amendment argument, must also fail. We would also question whether the petitioner can claim valuable property rights in a brand name that it has used in violation of the law and which apparently is contested.⁷

3. Granting the Carbolite Petition Would Be Bad Public Policy.

If FDA grants this petition, it will be effectively authorizing "low carbohydrate" nutrient content claims. Makers of other "low carb" foods will likely petition the agency for a defined "low carb" nutrient content claim, which FDA would be hard-pressed to deny. Allowing a "low carbohydrate" nutrient content claim would give FDA's blessing to the currently popular high-protein, low-carbohydrate diets, such as the Atkins Diet.

CMA and NCA believe this would be unfortunate. It has not yet been established that such low-carbohydrate diets are a safe way to lose weight.⁸ In addition, the message to reduce intake of total carbohydrates, or even "net effective carbohydrates," oversimplifies the current scientific understanding of the role of carbohydrates in nutrition (*see* footnote 4 above).

4. The Proposed "Carbohydrate Facts" Box Is Not Appropriately Included in a Petition Filed Under 21 U.S.C. § 343(r)(4)(A)(iii). It Would Require a Petition to Amend FDA's Nutrition Labeling Regulation.

The petition requests that FDA approve use of a "Carbohydrate Facts" box, placed adjacent to the Nutrition Facts box, that would distinguish "net effective carbohydrates" from other carbohydrates nutritionally.⁹ The request for permission to use a "Carbohydrate Facts" box is not appropriately included in a petition to use an implied nutrient content claim in a brand name. The proposed "Carbohydrate Facts" box is a form of nutrition labeling and should be the subject of a

⁷ See comments submitted by Universal Nutrition, dated December 18, 2002, stating that it is involved in ongoing litigation with Carbolite Foods over the Carbolite® trademark.

⁸ "... High-protein, low-carbohydrate diets have not been tested in long-term studies. We really need to know their long-term effects because these diets.... have effects that go well beyond weight loss.... these diets are high in saturated fat and cholesterol and so may set the stage for heart disease even as weight decreases.... high-protein, low-carbohydrate diets could cause kidney damage in some people." Walter C. Willett, *Eat, Drink, and Be Healthy*, Simon & Schuster, New York, 2001, p. 48.

⁹ The term "net effective carbohydrates" is not defined by FDA, and the petitioner has presented no evidence that it is commonly understood by consumers.

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separate petition to amend FDA's nutrition labeling regulation, 21 C.F.R. § 101.9. Turning to the substance of petitioner's request, as discussed above, CMA and NCA believe that considerably more data is needed before FDA could amend that regulation to allow the "Carbohydrate Facts" now being used by the petitioner. We therefore urge FDA to also deny this aspect of the petition.¹⁰

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For the foregoing reasons, we urge FDA to deny the petition.

Respectfully submitted,

/s/

Lawrence T. Graham
President

¹⁰ When CMA wished to distinguish stearic acid from other saturated fatty acids, CMA and the Cocoa Merchants Association petitioned FDA to amend its nutrition labeling regulations. If Carbolite® is permitted to distinguish different carbohydrates in a box outside but adjacent to the Nutrition Facts box, then chocolate manufacturers should be able to similarly distinguish stearic acid from other saturated fats on product labels.