



JAN 15 2003

Food and Drug Administration  
College Park, MD 20740

Carbolite® Foods, Inc.  
Attn: C. Gordon Brown, Ph.D.  
1325 Newton Avenue  
Evansville, Indiana 47715

Re: Docket No. 02P-0462

Dear Dr. Brown:

This letter responds to the petition you submitted on behalf of Carbolite® Foods, Inc. ("Carbolite®"), dated October 4, 2002, pursuant to section 403(r)(4)(A)(iii) of the Federal Food, Drug, and Cosmetic Act ("FDC Act" or "the Act") (21 U.S.C. § 343(r)(4)(A)(iii)) and 21 C.F.R. 101.69(o). The petition requests that the Food and Drug Administration ("FDA" or "the agency") approve the brand name "Carbolite" as an implied nutrient content claim in a brand name for use in the labeling of foods qualifying, as defined by FDA regulation, for "zero sugar" or "reduced sugar" claims. FDA filed this petition on October 7, 2002 (Docket No. 02P-0462), and published a notice in the Federal Register for a 30-day comment period on the petition (67 Fed. Reg. 72963, December 9, 2002). During this period, the agency received 11 comments from industry, trade groups, and a registered dietitian who is also a diabetes educator.

#### The Statutory and Regulatory Scheme.

A petition for a nutrient content claim in a brand name must comply with section 403(r)(4)(A)(iii) of the Act. 21 U.S.C. § 343(r)(4)(A)(iii). This section requires the Secretary (and by delegation, FDA) to grant a petition for the use of an implied nutrient content claim in a brand name, after notice and opportunity for public comment on the petition, if FDA finds that the claim is (1) not misleading, and (2) consistent with terms defined by regulation pursuant to section 403(r)(2)(A)(i) of the Act 21 U.S.C. § 343(r)(2)(A)(i). FDA must grant or deny such petition within 100 days of the date the petition is submitted, otherwise the petition shall be considered granted. 21 U.S.C. § 343(r)(4)(A)(iii). The 100-day deadline for Carbolite®'s petition is January 15, 2003.

Section 101.69(o) of FDA's regulations (21 C.F.R. § 101.69(o)) prescribes the process through which one can petition the agency for a nutrient content claim in a brand name. 21 C.F.R. § 101.69(o). A petition submitted pursuant to section 403(r)(4)(A)(iii) and 21 C.F.R. § 101.69(o) must include a statement identifying (1) the implied nutrient content claim, (2) the nutrient the claim is intended to characterize, (3) the corresponding term for characterizing the level of such nutrient as defined by regulation promulgated under section 403(r)(2)(A)(i) of the Act, and (4) the brand name of which the implied claim is intended to be a part,

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among other criteria. The petition should address why the use of the brand name as proposed will not be misleading, in addition to what information is required to accompany the claim or other ways in which the claim meets the requirements of sections 201(n) and 403(a) of the Act. 21 C.F.R. § 101.69(o).

The Carbolite® Petition.

The petition you submitted on behalf of Carbolite® requests that FDA approve the brand name “Carbolite” as an implied nutrient content claim in a brand name for use in the labeling of foods qualifying, as defined by FDA regulation, for “zero sugar” or “reduced sugar” claims, as follows:

- 1) The agency permit the brand name “Carbolite” in food labeling, including that it be prominently displayed on the principal display panel.
- 2) The Carbolite® food satisfies FDA’s requirements for either “zero sugar” or “reduced sugar” claims.
- 3) The food is labeled, as appropriate, with either (1) “zero sugar” or a defined synonym, or with the alleged implied synonyms “zero sugar carbs” or “0 sugar carbs”<sup>1</sup>; or (2) “reduced sugar” or a defined synonym.
- 4) The foods qualifying as “zero sugar” products are labeled with the required statement that the food is “low calorie,” “reduced calorie,” or “not a low calorie food,” as appropriate. The foods qualifying as “reduced sugar” products are labeled to disclose the percentage and quantitative reduction in sugars compared to a comparable reference food.
- 5) The Nutrition Facts panel identifies the number of grams of total carbohydrates, and separately, the grams of dietary fiber, sugar alcohols, and sugars.<sup>2</sup>
- 6) The information panel or another prominent label panel includes a “dietary guidance” statement with the following “model claim”:

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<sup>1</sup> Please note that the proposed “implied synonyms” “zero sugar carbs” or “0 sugar carbs” are not approved as sugar content claims under 21 C.F.R. § 101.60(c). Thus, they are not allowed on labeling for food products.

<sup>2</sup> The petition additionally states that “current labeling *may* (emphasis added) include a “Carbohydrate Facts” box which highlights *net effective carb* information.” See Petition, Section II.A.4, at 13 . Thus, under Carbolite®’s proposal, not all labeling would necessarily include this information.

Carbolite® products are especially [sic] formulated for sugar controlled diets, including weight loss diets restricting carbohydrates having a notable effect on blood sugar (net effective carbs), including carbohydrates from sugar (sugar carbs). Carbolite® products are not necessarily “light” or “low” in calories or fat. See Nutrition Facts for information on carbohydrate, fat, and calories.

FDA has carefully considered the petition requesting to use the brand name “Carbolite” as an implied nutrient content claim in a brand name, for use in the labeling of foods qualifying for “zero sugar” or “reduced sugar” claims. Based on this review and other relevant information, the agency denies the petition. The reasons for FDA's denial are set forth below.

The “Carbolite” Brand Name is Inherently Misleading.

Applying the criteria set forth in 21 C.F.R. § 101.69(o), the petition identifies that (1) the implied nutrient content claim is “Carbolite” (which is intended to imply that a product is reduced or low in sugar<sup>3</sup>); (2) sugar is the nutrient that the “Carbolite” brand name is intended to characterize; (3) “zero sugar” or “reduced sugar,” or a defined synonym, are the corresponding terms defined by regulation with which the implied claim in this brand name is allegedly consistent; and (4) “Carbolite” is the brand name intended to characterize the level of sugar in products qualifying for “zero sugar” or “reduced sugar” claims. Further, the petition contends that use of the “Carbolite” brand name on these products will not be misleading.

As explained above, a nutrient content claim in a brand name must be (1) truthful and not misleading, and (2) consistent with terms defined by regulation pursuant to section 403(r)(2)(A)(i) of the Act. 21 U.S.C. § 343(r)(4)(A)(iii). FDA finds that

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<sup>3</sup> The phrases “low in sugar” or “low sugars” in this letter are used in a generic sense, as are the phrases “low in carbohydrates” or “low carbohydrates.” None of these is an approved nutrient content claim, and should not be interpreted or implied as such from this letter.

the term “Carbolite” is inherently misleading. Moreover, FDA finds that the term “Carbolite” is not consistent with terms defined by FDA pursuant to section 403(r)(2)(A)(i).<sup>4</sup> Although FDA denies the petition on both grounds, this letter focuses specifically on why the agency concludes that the brand name “Carbolite” is inherently misleading, and perhaps even false.

The term “carbo” in “Carbolite” suggests that the nutrient that the implied claim refers to is “carbohydrates,” not “sugars.” The petition expressly admits this conclusion (see Petition at 9 (“the ‘Carbo-’ term . . . constitutes an implied reference to ‘carbohydrate’”)), which is supported by comments on the petition.

Because “lite” appears immediately adjacent to the term “carbo,” and “lite” in “Carbolite,” at a minimum, implies that the product is light or low in what it modifies, the term “Carbolite” implies that a product is reduced or low in carbohydrates. Thus, when viewing the brand name “Carbolite” on its face, a consumer would reasonably believe that the product is reduced or low in carbohydrates compared to a similar product, not that the product is reduced in sugars when compared to a similar product. In fact, FDA has received correspondence directly from a consumer who was confused by the labeling on Carbolite® chocolate bars. The consumer’s confusion was the direct result of labeling that included the “Carbolite” brand name, a “zero sugar carbs” claim, and nutrition information indicating that the chocolate bars contained 25-28 grams of carbohydrates (depending upon the flavor of the bar). In addition, in a comment and in direct correspondence to the agency, a diabetes educator explains that counting only a few carbohydrates instead of total carbohydrates on food labels misleads and confuses persons with diabetes. Only after consuming the Carbolite®-brand product under the mistaken belief that the product is low in carbohydrates, do persons with diabetes later discover that the product has raised their blood sugar levels. Comments on the petition further explain that “zero sugar” or “reduced sugar” foods are not the same as “low carbohydrate” foods, since a food that is reduced in sugars is not necessarily reduced in total

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<sup>4</sup> Under the second statutory element in section 403(r)(4)(A)(iii), an implied nutrient content claim in a brand name must be consistent with terms defined by FDA under section 403(r)(2)(A)(i). 21 U.S.C. § 403(r)(4)(A)(iii). Generally, a product bearing a nutrient content claim is misbranded unless the nutrient content claim uses a term defined by regulation to characterize the nutrient level. 21 U.S.C. § 343(r)(1)(A) and (r)(2)(A)(i). Under the exception provided by section 403(r)(2)(A), however, a nutrient content claim in a brand name is not required to use a defined term but only a term *consistent* with a defined term. 21 U.S.C. 343(r)(4)(A)(iii). Accordingly, whatever term a brand name uses to characterize the level of a nutrient, it must nevertheless be consistent with a term defined by regulation and not be misleading. The “Carbolite” brand name is not consistent with terms for nutrient content claims defined by FDA because (1) there are no terms defined to characterize the level of carbohydrates, and (2) “lite” is defined to characterize calories and fat (or sodium), not carbohydrates (see 21 C.F.R. § 101.56). A majority of the comments submitted in response to the petition asserted that this is a separate and adequate basis to support denial of the petition.

carbohydrates. Thus, comments support FDA's determination that the brand name "Carbolite" refers to reduced or low carbohydrates, not reduced or low sugars, and thus is inherently misleading.

Carbohydrates include fiber, sugars, sugar alcohols, and starch, among other substances. Ingredients such as hydrogenated starch hydrolysate, unbleached enriched flour, rice flour, bread flour, and tapioca starch are a few examples of carbohydrate ingredients found in Carbolite® brand food products.<sup>5</sup> Carbolite® brand products are not low in carbohydrates. On the contrary, several of the

Carbolite® brand product labels that were submitted with the petition<sup>6</sup> indicate that these products contain the same or substantially similar amounts of carbohydrates as similar products that do not substitute sugar alcohols for sugars ("comparable reference products"). See Petition at Appendix E. Use of the term "Carbolite" on products in which there is no reduction in carbohydrates compared to a similar product is not only inherently misleading, but is not truthful.

In addition, some comments contend that the term "Carbolite" is further misleading based upon FDA's regulation in 21 C.F.R. § 101.56 defining the term "lite." Both FDA and these comments conclude that the use of the term "lite" will lead some consumers to reasonably believe that a "Carbolite"-labeled product is light (or greatly reduced) in calories and/or fat. This conclusion is based on the fact that the term "lite" (or "light"), standing alone, has only been approved and used on food labels to characterize the level of calories and/or fat (and sometimes sodium). 21 C.F.R. § 101.56 As explained above, the most logical and reasonable conclusion regarding the use of the terms "carbo" and "lite" is that they refer to the carbohydrate content of the product, based upon their immediate proximity to one another. Nonetheless, the use of "lite" may further confuse and mislead a consumer because he or she is accustomed to viewing the term "lite" (or "light") only on labels of products that are reduced in calories and/or fat. But, most of the products identified in the petition are not, in fact, reduced in calories and/or fat.<sup>7</sup> Indeed, many of these products contain more calories and/or fat than the comparable reference product.

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<sup>5</sup> See selected pages "from Carbolite®'s website, printed on January 10, 2003, attached hereto at Appendix A. Although the petition provided labeling for 11 Carbolite® brand products, FDA visited Carbolite®'s website, located at <<http://www.carbolitedirect.com>>, and discovered in excess of 70 products, not including bulk, combo, or featured specials. All labels of these products, with the exception of a product labeled "At Last," bore the "Carbolite" brand name. The website also provided a list of ingredients and a form of nutrition information.

<sup>6</sup> Carbolite® brand product labels submitted with the petition include labels for the Carbolite® Chocolate Peanut Butter Bar, Carbolite® Chocolate Almond Bar, Carbolite® Chocolate Crisp Bar, Carbolite® Dark Chocolate Bar, Carbolite® Gummy Bears, Carbolite® Chewy Fruits Candy, Carbolite® Chewy Mints, and Carbolite® Jelly Beans.

<sup>7</sup> See "Comparison of Carbolite® Products and Similar Products," attached hereto at Appendix B.

The “Carbolite” Brand Name is Inherently Misleading in the Context of the Entire Labeling.

FDA finds that not only is the “Carbolite” brand name, standing alone, inherently misleading, but that the entire labeling as a whole is inherently misleading. Any petitioner submitting a petition for a nutrient content claim in a brand name pursuant to section 403(r)(4)(A)(iii) of the Act and 21 C.F.R. § 101.69(o) should address why the use of the brand name as proposed will not be misleading. Additionally, the petition should address what information is required to accompany the brand name or other ways in which the claim meets the statutory requirements of sections 201(n) and 403(a) of the Act. 21 C.F.R. § 101.69(o)(1). If the brand name is false or misleading, the petition will be denied under section 403(r)(4)(A)(iii).

The petition identifies and proposes to include three different items on labels bearing the “Carbolite” brand name. The proposed labeling items include (1) the term “zero sugar” or “reduced sugar,” or defined synonyms, with the requisite regulatory explanations; (2) the Nutrition Facts panel; and (3) a “model claim.” The petition states that the labeling *may* also include a “Carbohydrate Facts” box which highlights “net effective carbs.” See Petition, Section II.A.4, at 14. Even though FDA understands from the petition that not all of Carbolite®’s products may contain this Carbohydrate Facts box, the presence or absence of such box would not alter the agency’s conclusion that the “Carbolite” labeling as a whole is inherently misleading.

First, the petition states that products bearing the “Carbolite” brand name will also be labeled, as appropriate, with either (1) “zero sugar” or a defined synonym, or with the alleged implied synonyms “zero sugar carbs” or “0 sugar carbs,” or (2) “reduced sugar” or a defined synonym. In addition, the foods qualifying as “zero sugar” products would be labeled with the required statement that the food is “low calorie,” “reduced calorie,” or “not a low calorie food,” as appropriate, while the foods qualifying as “reduced sugar” products would be labeled to disclose the percentage and quantitative reduction in sugars compared to comparable reference product. The fact that “zero sugar” or “reduced sugar,” or their defined synonyms, would appear on the Carbolite® brand label would not necessarily suggest to the consumer that the term “Carbolite” means reduced or low in sugars.

Based upon comments on the petition, including one from a diabetes educator, as well as our predictive judgment, FDA believes that a reasonable consumer would not understand, when looking at the labeling as a whole, that “Carbolite” is intended to mean that the product is reduced or low in carbohydrates derived

from sugars, and more specifically, carbohydrates other than sugar alcohols. Further, FDA does not believe that such a consumer would understand that the “Carbolite” brand name, in conjunction with other information on the label, is not intended to mean reduced or low in total carbohydrates. Even with the addition of the terms “zero sugar” or “reduced sugar” on the label, FDA believes that a reasonable consumer would still be confused about the meaning of “Carbolite.” Indeed, comments on the petition and those submitted directly to the agency confirm that consumers are confused by “Carbolite” in the context of its entire labeling. A label containing the “Carbolite” brand name and “zero sugar” or “reduced sugar” claims implies that the product is not only reduced or low in total carbohydrates, but is also reduced or low in sugars.

Second, the petition identified the Nutrition Facts panel as a means of clarifying the meaning of the “Carbolite” brand name. The petition states that the Nutrition Facts panel would set forth the number of grams of total carbohydrates, and separately, the grams of dietary fiber, sugar alcohols, and sugars. The Nutrition Facts panel would not cure the misleading quality in the “Carbolite” brand name. In fact, this panel only highlights that a product bearing “Carbolite” on its label would not conform to the low carbohydrate claim implied by the brand name. If a consumer were to compare the total grams of carbohydrates in a Carbolite® brand product to a similar product on the market, he or she would realize that these products contain the same or substantially similar amounts of carbohydrates. Thus, Carbolite®’s proposed label would confuse consumers.

Separately identifying the amounts of dietary fiber, sugar alcohols, and sugars in a “Carbolite”-labeled product also does not correct the “Carbolite” brand name from being inherently misleading. Most Carbolite® products are different from similar products in that their sugars have been replaced with sugar alcohols such as maltitol, erythritol, and hydrogenated starch hydrolysates. See Petition at 3. According to the petition, the reason for this substitution is to lower the amount of carbohydrates having a notable effect on blood sugar levels (including sugars) to manage diabetes mellitus and/or achieve weight loss. See Petition at 2. The agency does not believe, however, that a reasonable consumer understands the difference between sugars and sugar alcohols. Indeed, one consumer, who wrote directly to FDA, asked whether maltitol (i.e., a sugar alcohol) is “really a carbohydrate.” In light of this evidence, separately identifying the amounts of dietary fiber, sugar alcohols, and sugars in the Nutrition Facts panel does not make “Carbolite” truthful and nonmisleading. Nor does it necessarily indicate to a consumer that “Carbolite” refers to reduced or low sugars, rather than carbohydrates.

Third, the petition also proposes to use a “model claim” to clarify the meaning of the term “Carbolite.” On the information panel or other prominent display panel, the petition proposes to include the following “model claim” on product labels bearing the “Carbolite” brand name:

Carbolite® products are especially [sic] formulated for sugar controlled diets, including weight loss diets restricting carbohydrates having a notable effect on blood sugar (net effective carbs), including carbohydrates from sugar (sugar carbs). Carbolite® products are not necessarily “light” or “low” in calories or fat. See Nutrition Facts for information on carbohydrate, fat, and calories.

Petition at 6.

It remains unclear from this statement that “Carbolite” implies reduced or low in sugars. In fact, it suggests that there are carbohydrates other than sugars that are being restricted. See Petition at 6 (the model claim states: “restricting carbohydrates having a notable effect on blood sugar (net effective carbs), *including* carbohydrates from sugar (sugar carbs)” (emphasis added)). Carbohydrates affecting blood sugar levels include sugars, as well as starches. This fact is significant because the major source of carbohydrates in the United States is starch. Thus, “net effective carbs” and “sugar carbs” are not the same. Nowhere in the petition, however, is it stated that Carbolite® brand products will be free of or low in starch, in addition to sugars. The “Carbolite” brand name will be used on products that meet “zero sugar” or “reduced sugar” claims, but the products are not required to be low in starch. This could create serious health consequences for individuals (e.g., persons with diabetes) consuming the product believing it to be low in carbohydrates that affect blood sugar levels. Thus, contrary to the model claim, Carbolite® brand products are not restricted in carbohydrates that have a notable effect on blood sugar. Further, the products may not be low in carbohydrates; many contain the same or substantially similar amounts of carbohydrates as similar products. The model claim, therefore, itself is inherently misleading, and cannot save the “Carbolite” brand name from being inherently misleading.

Moreover, the statement in the “model claim” that Carbolite® brand products are “formulated for sugar controlled diets, including weight loss diets restricting carbohydrates,” implies, on its face, that restricting carbohydrates leads to weight loss. See Petition at 6. Some comments contend that it has not been established that low-carbohydrate diets are a safe way to lose weight. A reasonable consumer reading Carbolite®’s “model claim” would be misled into

believing that products that are not reduced in calories or fat, but that are lower in carbohydrates, would help them lose weight. This is misleading given that Carbolite® brand products are not necessarily reduced or low in carbohydrates. Additionally, even if Carbolite® brand products were reduced or low in carbohydrates, the “model claim” would be misleading because it suggests that diets low in carbohydrates but high in calories and/or fat lead to weight loss.

Finally, the petition identifies and proposes that Carbolite® brand labeling may include a “Carbohydrate Facts” box. The proposed Carbohydrate Facts box explains how many “net effective carbs” are contained in a “Carbolite”-labeled product. As supported by the comments, FDA believes that a reasonable consumer is likely to be confused by what the numbers in the Carbohydrate Facts box mean. When viewing the Carbohydrate Facts box in the context of the entire “Carbolite” labeling, it is not clear what “net effective carbs” refers to and how these relate to the amount of total carbohydrates or individual carbohydrates contained in the product. Thus, FDA believes that the Carbohydrate Facts box, in conjunction with the “Carbolite” brand name, would lead a reasonable consumer to falsely conclude that the product contains only a few total carbohydrates. The information about total carbohydrates listed in the Nutrition Facts panel does not solve this problem. Rather, viewing the “Carbolite” brand name, the Carbohydrate Facts box, and Nutrition Facts panel together, a consumer is likely to become even more confused. For example, one consumer evidenced his own confusion in a letter to FDA about a Carbolite® brand product label: “Do these bars contain 27 grams or two grams of carbohydrate?”.

With respect to these labeling proposals, and in particular, the Carbohydrate Facts box, a comment from a registered dietitian and certified diabetes educator asserted that “[t]he nutrition claims requested by Carbolite . . . are misleading to people with diabetes.” C. Schwide-Slavin Comment. This commenter explains that the

additional box with Net Carbohydrate Effect has led people with diabetes to take incorrect insulin doses and/or have uncontrolled blood sugars from diet control due to underestimating the carbohydrate impact on blood sugars. A number of my patients have alerted me to this problem . . . .

Id. According to this health care professional, Carbolite® brand labeling misleads persons with diabetes, a population for which Carbolite® brand products are intended. See Petition at 2 (stating that “Carbolite® brand food products are appropriate for use in diets intended for the management of diabetes mellitus”).

Despite the four labeling proposals discussed above, the “Carbolite” brand name remains inherently misleading. None of the labeling proposals alone is sufficient to make the use of the brand name truthful and not misleading. Further, when viewed together in the context of the label as a whole, these labeling proposals effectively render the term “Carbolite” as inherently misleading as it is standing alone. Moreover, the proposed “model claim” not only adds to the misleading nature of the brand name, but also renders the label misleading with respect to safe weight loss and dieting. FDA’s conclusion, which is substantially supported by comments received in response to the petition, is that the “zero sugar”/“reduced sugar” claims, the Nutrition Facts panel, the proposed “model claim,” and the proposed “Carbohydrate Facts” box, do not serve, either separately or in combination, to change the nature of this claim from one that is inherently misleading to one that is not.

Prohibiting the “Carbolite” Brand Name Does Not Violate the First Amendment.

FDA’s denial of Carbolite®’s petition seeking authorization to use “Carbolite” as an implied nutrient content claim in a brand name for use in the labeling of foods qualifying for “zero sugar” or “reduced sugar” claims does not violate the First Amendment. Speech that is false or inherently misleading is not protected by the First Amendment and may be prohibited. See Central Hudson Gas & Elec. Corp. v. Public. Serv. Comm’n, 447 U.S. 557, 563-64 (1980). Throughout this letter, we have explained that the “Carbolite” brand name is inherently misleading. This finding is based, in part, on the fact that “Carbolite” implies that a product is reduced or low in carbohydrates instead of sugars. Moreover, none of the additional labeling proposed in the petition renders the “Carbolite” brand name truthful and not misleading. Indeed, some of these labeling proposals are, in and of themselves, inherently misleading. Accordingly, because the “Carbolite” brand name is inherently misleading, FDA’s decision to deny the petition does not constitute a violation of Carbolite®’s First Amendment rights.

Prohibiting the “Carbolite” Brand Name Does Not Constitute a Taking Without Just Compensation in Violation of the Fifth Amendment.

The petition asserts that FDA’s prohibition of the “Carbolite” brand name would constitute a taking without just compensation in violation of the Fifth Amendment. In support of this argument, the petition contends that the “Carbolite” brand name and trademark have been used for three years and are valuable and important business assets; and, in addition, there is national recognition and business goodwill associated with it. As a result, the petition concludes that FDA’s failure to approve the petition would be tantamount to putting Carbolite® out of business, and thereby constitute a taking of property without just compensation.

FDA does not agree that its decision not to authorize the term “Carbolite” as an implied nutrient content claim in a brand name constitutes a taking without just compensation in violation of the Fifth Amendment. A standard takings analysis under the Fifth Amendment reveals that despite any regulatory action or decision made on the petition by FDA, Carbolite® does not have a cognizable property interest for which it can be compensated. A compensable taking requires that (1) Carbolite® possess a compensable property interest (see, e.g., Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1027-1030 (1992); see also M & J Coal Co. v. United States, 47 F.3d 1148, 1153-54 (Fed. Cir. 1995), cert. denied, 516 U.S. 808 (1995)), and (2) FDA’s actions actually constitute a taking of that property. See M & J Coal Co., 47 F.3d at 1153-54; Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978).

In order to have a compensable property interest, that interest must be lawful. Broughton Lumber Co. v. United States, 30 Fed. Cl. 239, 243 (1994); see also Provimi, Inc. v. United States, 680 F.2d 111, 113-14 (Ct. Cl. 1982) (holding that one cannot have a cognizable property interest in an illegal product). Carbolite® cannot legitimately assert a compensable property interest in the “Carbolite” brand name because such use of a nutrient content claim is unlawful until approved and authorized by FDA. 21 U.S.C. § 343(r)(4)(A)(iii); 21 C.F.R. § 101.13(q)(7).<sup>8</sup> Yet, in direct contravention of the nutrient content claim regulations implemented more than nine years ago, Carbolite® has unlawfully used this brand name for the past three years. Comments on the petition assert that Carbolite® has been profiting from the use of an illegal name for three years. Because the “Carbolite” brand name was unlawful from the start, it has never been a property interest the deprivation of which would require compensation under the Fifth Amendment. See Lucas v. South Carolina Coastal Council, 112 S.Ct. 2886, 2899, 2901-902 (1992) (stating that whether there was a taking when a coastal preservation law prevented development of property depended upon whether the restrictions existed at the time the property was purchased).<sup>9</sup>

Although a trademark can be a lawful and legally protected property interest, the grant of a trademark “is not a *carte blanche* to use the mark for any and all purposes.” Bronco Wine Co. v. United States, 997 F.Supp. 1309, 1317 (E.D. Cal. 1996). Rather, “[i]mplicit in such a grant is the obligation to use the trademark in compliance with other valid laws, even if . . . such laws limit the use

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<sup>8</sup> See also Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acids, and Cholesterol Content of Food, Final Rule, 58 Fed. Reg. 2302, 2312 cmt. 27 (“It would make little sense for Congress to have included a petition process with such tight timeframes if it intended that a claim could appear while the petition for such claim is under agency review.”).

<sup>9</sup> See also 58 Fed. Reg. at 2397 (“[T]here is no regulatory taking under the fifth amendment if a manufacturer is required to alter its brand name when that trade name asserts, expressly or by implication, a nutrient content claim that has not been approved by FDA.”).

of the trademark.” Id. The fact that the trademark is the same as the unlawful “Carbolite” brand name indicates that Carbolite® knew (or should have known) that the trademark would also be subject to FDA regulations governing nutrient content claims. FDA’s decision to deny the petition does not nullify Carbolite®’s trademark. Rather, Carbolite® must comply with the prescribed regulatory process and petition the agency for a regulation that would provide appropriate nutrient content claim terms with which its brand name and trademark would be consistent and not misleading. See, e.g., Meserey v. United States, 447 F.Supp. 548, 554 (D. Nev. 1977) (“Plaintiff has not been denied his property. He is denied the right to introduce goods into commerce unless they are in compliance with the [FDC Act].”).

Even assuming that Carbolite® has a compensable property interest in its brand name and trademark, FDA’s decision to deny the petition still does not amount to taking in violation of the Fifth Amendment because FDA’s decision does not actually constitute a taking of property. Whether or not governmental action actually constitutes a taking of property is determined by evaluating (1) the character of the governmental action, (2) the economic impact of the governmental action, and (3) the extent to which the governmental action has interfered with investment-backed expectations. See Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978).

First, as to the character of FDA’s action, it is well established that courts “afford particular deference to governmental action taken in order to protect the public interest in health, safety, and welfare.” See, e.g., Keystone Bituminous Coal Ass’n v. DeBenedictis, 480 U.S. 470, 488 (1987); Penn Central, 438 U.S. at 125. This factor alone weighs heavily against finding a taking. See Keystone, 480 U.S. at 488. In fact, regulatory actions taken to protect the public health are rarely held to constitute takings. See Porter v. DiBlasio, 93 F.3d 301, 310 (7th Cir. 1996) (holding that an action taken to protect the public health falls within the class of property deprivations for which the Fifth Amendment does not require compensation). Here, FDA’s denial of the petition protects the public interest in health by ensuring that the “Carbolite” labeling will not induce consumers to purchase and consume Carbolite® brand products on the mistaken belief that these products are reduced or low in carbohydrates.

Government and industry surveys consistently find that a majority of consumers refer to a product's label the first time that they purchase a food product.<sup>10</sup> Moreover, according to an FDA survey, the most frequently reported label use and the one with the most increased usage is "to see how high or low the food is in things like calories, salt, vitamins, fat, etc."<sup>11</sup> These surveys show that consumers use food labels and labeling to inform their purchasing and nutrition decisions. As supported by comments on the petition, FDA believes that consumers are and would be confused by the "Carbolite" brand name and the proposed labeling. For example, a registered dietitian and diabetes educator opposed the petition in an effort to protect her patients' and clients' from being misled by "Carbolite" and the "net effective carb" principle enlisted on the "Carbolite® brand label. The very purpose of regulating food labeling claims is to ensure that consumers have access to nutrition information<sup>12</sup> that is truthful, reliable, understandable, scientifically valid, and not misleading." Food Labeling: Nutrient Content Claims, General Principles, Petitions, Final Rule, 58 Fed. Reg. 2302, 2394 (Jan. 6, 1993). Labeling information satisfying these criteria will enable consumers to make more healthful and informed food choices. In light of these surveys and FDA's determination that the "Carbolite" brand name and proposed labeling would mislead consumers, FDA's decision to deny the petition serves to protect and promote the public health.

Second, whether governmental action constitutes a taking also considers the action's economic impact. It is well established that a regulation's economic impact may be great without rising to the level of a taking under the Fifth Amendment. See Pace Resources, Inc. v. Shrewsbury Township, 808 F.2d 1023 (3rd Cir. 1987), cert. denied, 482 U.S. 906 (1987). An analysis of the economic impact of governmental action involves looking not only at what may be lost, but also the nature and extent of the interference with rights in the property as a whole. See id. FDA's decision to deny the petition does not permanently deprive Carbolite® of an economically viable use of its brand name or trademark. In order to continue to use this brand name and trademark, however, Carbolite® must submit a petition to define a term in the nutrient content claim regulations with which the "Carbolite" brand name and trademark will be consistent and not misleading. The financial burden of following these processes does not amount to a taking.

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<sup>10</sup> See Derby, B.M. and A.S. Levy, "Do food labels work? Gauging the effects of food labels pre- and post-NLEA," in Handbook of Marketing and Society 372-398 (P.N. Bloom & G.T. Gundlach eds. 2001) (finding that approximately 75 percent of consumers refer to the label); Food Marketing Institute, "Trend in the United States: Consumer Attitudes and the Supermarket 1997," at 17-18, 66-67, 70-73, 75 (Washington, DC 1997) (finding that approximately 51 percent of consumers refer to the label).

<sup>11</sup> See Derby, B.M. and A.S. Levy, "Do food labels work? Gauging the effects of food labels pre- and post-NLEA," in Handbook of Marketing and Society 372-398, supra.

<sup>12</sup> Although the phrase "nutrition information" is often interpreted as referring to Nutrition Facts, it is used here in the only the most generic sense.

Finally, whatever economic impact is suffered by Carbolite® as the result of FDA's denial, it is outweighed by Carbolite®'s lack of reasonable investment-backed expectations in its brand name and trademark. Whether investment-backed expectations are reasonable depends upon considerations of the power of the state to regulate in the public interest and the regulatory environment. See Pace Resources, 808 F.2d at 1033. It would be unreasonable for Carbolite® to argue that it was not on notice that the propriety of its brand name and trademark might be challenged by FDA. See, e.g., FHA v. The Darlington, Inc., 358 U.S. 84, 91 (1958) ("Those who do business in the regulated field cannot object if the legislative scheme is buttressed . . . to achieve the legislative end."). Moreover, it is difficult to see how Carbolite® could have any reasonable investment-backed expectations with respect to the Carbolite brand name and trademark when these have been used unlawfully from the start. See 58 Fed. Reg. at 2397 (Jan. 6, 1993) (stating that there is no regulatory taking under the Fifth Amendment if a manufacturer must alter its brand name when that brand name asserts, expressly or by implication, a nutrient content claim that has not been approved by FDA).

#### Summary and Conclusion

To summarize, FDA denies Carbolite®'s petition requesting an implied nutrient content claim in the brand name "Carbolite" for use in the labeling of foods qualifying, as defined by FDA regulation, for "zero sugar" or "reduced sugar" claims. This denial is based upon a finding that the "Carbolite" brand name is inherently misleading, in violation of the first statutory element required under section 403(r)(4)(A)(iii). The labeling that the petition proposes in addition to the brand name does not change FDA's determination. Indeed, the proposed model claim creates greater confusion for the reasons set forth above.

The agency's denial does not permanently prohibit use of the "Carbolite" brand name. Rather, we remind Carbolite® that there is process prescribed in FDA regulations pursuant to section 403(r)(2)(A) for petitioning the agency for a regulation that would define an appropriate nutrient content claim term with which the "Carbolite" brand name could be consistent. Indeed, some comments argued, and FDA agrees, that the petition process under section 403(r)(4)(A)(iii), with its abbreviated timeframe, is not a suitable or appropriate vehicle to consider the "Carbolite" claim. These comments suggested that because Carbolite® effectively seeks a new "low carbohydrate" nutrient content claim, it should submit a petition pursuant to 21 C.F.R. § 101.69(m) and section 403(r)(4)(A)(i) of the Act. Any request to amend the regulations under section 403(r)(4)(A)(i)

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should provide a basis for why a new defined term is one with which “Carbolite” could be consistent. If a regulation is established, a new petition submitted under section 403(r)(4)(A)(iii) for an implied nutrient content claim in the brand name “Carbolite” could show why “Carbolite” satisfies the requirements of sections 403(r)(4)(A)(iii), 403(a), and 201(n) of the Act. This petition should provide data and information necessary to demonstrate that the use of this term would not be false or misleading, when used alone and in the context of the entire label.

Sincerely,

A handwritten signature in black ink, appearing to read "L. Robert Lake". The signature is fluid and cursive, with the first letters of each word being capitalized and prominent.

L. Robert Lake  
Director of Regulations and Policy  
Center for Food Safety  
and Applied Nutrition

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