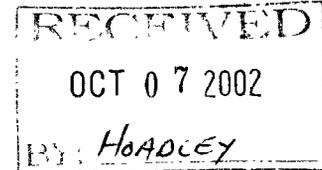


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Petitioner: Carbolite® Foods, Inc.

October 4, 2002

Address: 1325 Newton Ave., Evansville, IN 47715

Subject: Petition for the Use of an Implied Nutrient  
Content Claim in the Brand Name "Carbolite®"Office of the Nutritional Products, Labeling and  
Dietary Supplements (HFS 800)  
Food and Drug Administration  
Department of Health and Human Services  
Washington, DC 20204**To Whom It May Concern:**

The undersigned, C. Gordon Brown, Ph.D., Vice President - Research and Quality Systems, submits this petition on behalf of Carbolite® Foods, Inc.

("Carbolite®"), pursuant to section 403(r)(4) of the Federal Food Drug and Cosmetic Act ("FD&C Act"), to ensure that Carbolite® may continue to use the company brand name, "Carbolite®," for its line of "zero sugar" and "reduced sugar" food products. 21 U.S.C. 343(r)(4). These foods are specially formulated for use in dietary regimes restricting the intake of carbohydrates which have a noted effect on blood sugar levels, including "sugars" as defined under FDA regulations. 21 C.F.R. 101.9(c)(6)(ii). All of the items specified in 21 C.F.R. 101.69(o) are included in or attached to this petition.

**I. Established Conditions of Use of "Carbolite®" Brand Name for "Zero Sugar" and "Reduced Sugar" Foods****A. Background**

The Carbolite® brand name is a registered trademark owned by Carbolite® Foods, Inc. which is used exclusively for the line of "zero sugar" and "reduced sugar" food products marketed by and on behalf of the company. These

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products are specially formulated for use as part of sugar-controlled diets, including dietary regimes designed to limit the overall intake of carbohydrates having a noted effect on blood sugar (i.e., “*net effective carbs*”). While Carbolite® brand food products are appropriate for use in diets intended for the management of diabetes mellitus, Carbolite® brand products currently are most commonly used by consumers following “low carbohydrate” weight loss diets (i.e., “low carbohydrate diets”). Two of the most popular low carbohydrate diets are characterized in the best selling books, “Dr. Atkins New Diet Revolution”, and “Sugar Busters”. See Appendix A. Low carbohydrate diets achieve weight loss through metabolic processes that are produced naturally in the body when the dietary intake of *net effective carbs* is restricted below certain threshold levels. See Appendix B. Metabolic changes occur when restrictions are made on the intake of carbohydrates that affect insulin levels. The most significant of these metabolic changes is the body’s increased reliance on fat rather than carbohydrates as an energy source.

*Net effective carbs* include carbohydrates that are metabolized in a manner that affects blood sugar levels and insulin release, and encompasses starches and sugars. The fraction of *net effective carbs* in a food that is contributed by “sugars” is commonly termed “*sugar carbs*” by Carbolite®. See [www.CarbSolutions.com](http://www.CarbSolutions.com); [www.ketogenics.com](http://www.ketogenics.com); [www.my-pastalia.com](http://www.my-pastalia.com); [lowcarbchocolates.com](http://lowcarbchocolates.com).

The distinction that is made in low carbohydrate diets between *net effective carbs* and the “non-effective” carbohydrates which have no significant effect on blood sugar/insulin release (e.g., sugar alcohols), is comparable to FDA’s classification of carbohydrates under the “fermentable carbohydrate” definition. For example, for purposes of sugar alcohol/dental caries health claims, FDA regulations define

“fermentable carbohydrate” to exclude sugar alcohols, and impose restrictions on both “fermentable carbohydrate” and “sugars” for foods sweetened with sugar alcohols. *See* 21 C.F.R. 101.80. Sugar alcohols constitute “carbohydrate,” as defined by FDA, but are similarly excluded from the scope of both “fermentable carbohydrate”, and *net effective carbs*. The distinction that is made in low carbohydrate diets between *sugar carbs* and “non-effective” carbohydrates is comparable to the distinction FDA policy makes by defining “sugars” and “sugar alcohols” as separate types of “carbohydrate.” 21 C.F.R. 101.9(6)(ii)-(iii). FDA was persuaded to abandon its original proposal which would have defined “sugars” to include “sugar alcohols,” in order to account for the metabolic distinctions which justify “sugar free” claims for foods sweetened with sugar alcohols. *See* 58 Fed. Reg. 2302, 2325 (January 6, 1993). These are the same metabolic distinctions that have importance in low carbohydrate weight loss diets. To adhere to the “low carbohydrate” restrictions of these regimes, dieters must monitor and limit their intake of *net effective carbs*, including those contributed by *sugar carbs*. In contrast to low calorie weight loss diets, no restriction is placed on calories.

Carbolite® foods are formulated to carefully control the use of all ingredients that are sources of carbohydrate to reduce the amount of net effect carbs contributed to the diet compared to conventional food alternatives. Carbohydrate levels are reduced principally through the use of sugar alcohol sweeteners in place of the sugars that are contained in conventional foods. Maltitol, erythritol, and hydrogenated starch hydrolysates are commonly used in Carbolite® formulations. In contrast to sugars, these sweeteners are absorbed from the gut slowly and have no notable effect on blood sugar levels or insulin release. Carbolite® products are significantly reduced in *net effective*

*carbs* compared to conventional foods, principally because of the reductions achieved in *sugar carbs*. As a result, Carbolite® foods are readily incorporated into low carbohydrate weight loss diets, and other sugar-controlled dietary regimes.

For most currently marketed Carbolite® foods, *sugar carbs* have been virtually eliminated from the formulations, and the finished food products qualify as “zero sugar,” as defined by FDA regulations. 21 C.F.R. 101.60(c)(1). *See* page 23. For other Carbolite® food products, *sugar carbs* have been substantially reduced but not eliminated, and the finished food products qualify as “reduced sugar,” as defined by FDA regulations. 21 C.F.R. 101.60(c)(5). These Carbolite® foods contain only small amounts of sugar. For example, Carbolite® cheesecake is reduced in sugar by 95 percent compared to the reference food, and contains only 1.45 grams of sugar per RACC. *See* page 24. Carbolite® Inc. plans to expand the line of Carbolite® brand food products to include a variety of new “zero sugar” and “reduced sugar” foods including, but not limited to, ice cream, cookies and other baked products, and tabletop sweeteners.

The current line of Carbolite® brand foods features flavorful confectionery and dessert products of the types that typically are forbidden to weight loss dieters. By providing enjoyable food choices to dieters, Carbolite® foods promote successful weight loss by helping dieters avoid feelings of deprivation that may otherwise arise, and motivating sustained adherence with low carbohydrate dietary regimens.

**B. Summary of Proposed Criteria for Foods Bearing the “Carbolite®” Brand Name In Labeling**

Based on the currently established conditions of use for Carbolite® foods, Carbolite® Foods, Inc. requests that FDA approve the Carbolite® brand name under 21 C.F.R. 101.69(o), formally authorizing its use in the labeling of foods qualifying for the

claims “zero sugar” or “reduced sugar,” as defined under FDA regulations, in accordance with the following criteria:

1. **Placement and Prominence.** The Carbolite® brand name is permitted in food labeling, including prominently displayed on the principal display panel (“PDP”) for foods manufactured, sold, distributed, or marketed by or on behalf of Carbolite® Inc.
  
2. **Benchmark Expressed Nutrient Content Claims.** The Carbolite® food conforms with FDA requirements for either “zero sugar” or “reduced sugar” claims:
  - (a) **Zero Sugar.** (i) the food satisfies the criteria to be labeled as “sugar free,” “free of sugar,” “no sugar,” “zero sugar,” “without sugar,” “sugarless,” “trivial source of sugar,” “negligible source of sugar,” or “dietarily insignificant source of sugar” under 21 C.F.R. 101.60(c)(1); (ii) the food is labeled with “zero sugar” or a defined synonym, or with the implied synonyms, “zero *sugar carbs*” or “0 *sugar carbs*” under 21 C.F.R. 101.65 (a),(c)(3); and (iii) the food is labeled with the required disclaimer that the food is “low calorie,” “reduced calorie,” or “not a low calorie” food.
  
  - (b) **Reduced Sugar.** (i) the food satisfies the criteria to be labeled as “reduced sugar,” “reduced in sugar,” “sugar reduced,” “less sugar,” “lower sugar,” or “lower in sugar” under 21 C.F.R. 101.60(c)(5) (i.e., at least 25% reduced sugar); (ii) the food is

labeled with “reduced sugar” or a defined synonym; and (iii) the food discloses the percentage and quantitative reduction in sugars compared to the reference foods (e.g., cheesecake).

3. **Nutrition Facts.** The Nutrition Facts sets forth the number of grams of total carbohydrates, and separately, the grams of dietary fiber, sugar alcohols, and sugars.
4. **Dietary Guidance.** The information panel or another prominent label panel includes a dietary guidance statement which includes a disclosure that Carbolite® foods are not necessarily light or low in calories, fat, or sodium.

**Model Claim:** *“Carbolite® products are especially 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”.*

## **II. The Carbolite® Brand Name is Truthful, Non Misleading and Consistent with Governing Law and Policy**

Section 403(r)(1)(A) of the FD&C Act defines an “implied claim” to mean a claim “which by implication . . . characterizes the level of any nutrient” in the food.

Section 403(r)(4)(A)(iii) provides that, “any person may petition [FDA] for permission to use an implied claim . . . in a brand name.” This section further provides that FDA “shall grant the petition if [FDA] finds that such claim is not misleading and is consistent with terms defined by [FDA] under [section 403(r)(2)(A)(i)].” (Emphasis added). This standard is similar, but not identical, to the standard applied to petitions seeking approval

of new terms constituting synonyms for terms defined by FDA under section 403(r)(4)(A)(iii).

While the “consistent with” standard is not specifically defined by statute, the plain language clearly is distinguished from the policy that has been developed for nutrient content claims of general application. The English language meaning of “consistency” suggests that the policy applied to brand names should harmonize and not conflict with existing policy, but must not be held rigidly the same. “Consistency” is defined to include the following concepts: “agreement or logical coherence,” “compatibility or agreement among successive acts, ideas, or events.” *See Webster’s New Riverside University Dictionary* at 301 (1994). Synonymous ideas include, “logical agreement between things or parts,” “coherence,” “congruity,” and “correspondence.” *See Rogets II The New Thesaurus* at 205 (1988).

In contrast to implied claims in a brand name, implied claims that are used apart from a brand name, like expressed claims, are subject to a more restrictive standard under the FD&C Act. Section 403(r)(2)(A) provides that “[e]xcept as provided” for petitions for implied claims in a brand name, an expressed or implied nutrient content claim “may be made only if the characterization of the level made in the claim uses terms which are defined in [FDA] regulations . . . .” This more restrictive standard is codified in FDA regulations concerning implied claims generally, providing “[a]n implied nutrient content claim can only be made . . . if the claim uses one of the terms described in this section in accordance with the definition for that term . . . [and] is made in accordance with the general requirements for nutrient content claims in section 101.13 . . . .” 21 C.F.R. 101.65(a)(1)-(2). This standard cannot reasonably be applied to restrict implied

claims in brand names in view of the specific statutory exclusion protecting such brand names. Moreover, in view of this exclusion, the agency must exercise particular care in construing nutrient content claim regulations of general application in the context of brand name petitions to ensure that implied claims in brand names are protected from undue restriction. *See, e.g.,* 21 C.F.R. 101.13(q)(7) (providing that “implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the [FDA]”).

In sum, the statutory standard requires FDA to approve petitions for the use of implied claims in a brand name where the conditions of approval harmonize – and do not conflict – conceptually with the existing body of regulations, and the claim is otherwise used in a manner that is nonmisleading. Since approving brand names that overtly conflict with existing regulations would seem to present an obvious risk of consumer deception, the “consistency” standard for approval of brand names appears ultimately to amount to an antideception standard. Accordingly, where an implied claim in a brand name is sufficiently congruent with existing policy to be understood by consumers in the context of use, and is otherwise nonmisleading, the statute requires FDA to approve the brand name. This construction of FDA’s statutory obligations is consistent with FDA’s duties under the First Amendment.

The commercial importance and informational value of brand names in the effective marketing of food products cannot be overstated. The flexible antideception standard established by statute for the approval of brand names respects the considerable intellectual property value of this form of commercial speech. The antideception standard provides food manufacturers with much needed room for innovation in the

development of implied claims for the confined use in brand names used by an individual company. At the same time, the policies requiring consistency and uniformity in the use of terms of general application remains unaffected.

**A. “Carbo” Term in Carbolite® Brand Name**

**1. Carbohydrate Abbreviations**

Under the established conditions of use described above, the “Carbo-“ term that is embedded in the Carbolite® brand name constitutes an implied reference to “carbohydrate.” The “Carbo-“ term is truthful and nonmisleading, and consistent with FDA policy permitting abbreviations to be used for the declaration of nutrients in food labeling. Under section 101.9(c)(13)(ii)(B), the term “carb” is authorized for use as a component of abbreviations designated for “total carbohydrate” (“total carb”) and “other carbohydrate” (“other carb”). “Carbo-“ is consistent with and not in conflict with FDA regulations in this regard.

**2. Reliance on “Zero Sugar” and “Reduced Sugar” Expressed Nutrient Content Claims**

The Carbolite® brand name is used exclusively for “zero sugar” and “reduced sugar” foods that have been formulated with sugar alcohol sweeteners as alternatives to sugar-sweetened conventional foods for use in low carbohydrate weight loss diets, and other sugar-controlled diets. Because Carbolite® foods are formulated as alternatives to similar conventional foods, conceptually, all products are “reduced sugar” foods compared to reference conventional foods. *See* 21 C.F.R. 101.13(j)(1)(B). Nonetheless, for purposes of this petition, the expressed nutrient content claims, “zero sugar” and “reduced sugar,” as defined by FDA regulations, serve as the expressed nutrient content claims which function as regulatory benchmarks defining the Carbolite®

brand name. While these expressed claims characterize the level of “sugars” rather than “carbohydrates” in food (i.e., “total carbohydrate” or “other carbohydrate” as defined by FDA regulations), these terms nonetheless function as an appropriate basis for ensuring that the Carbolite® brand name is truthful, nonmisleading and consistent with applicable legal requirements. Under current FDA policy, no expressed nutrient content claims for carbohydrates exist, other than the expressed sugar content claims relied on here. These claims may serve to define the Carbolite® brand name in accordance with section 101.69(o), and related FD&C Act requirements.

Defining the Carbolite brand name with reference to expressed sugar content claims is consistent with the presumption that has been established historically in FDA food labeling policy between “sugars” claims and “weight loss/control” claims. *See* 21 C.F.R. 105.66 (1990)(regulating sugar content claims before the NLEA for “foods for special dietary use” relating to weight control). *See* 56 Fed. Reg. 60421, 60435 (November 27, 1991)(recognizing that consumers associate the absence of sugar with weight control claims); 21 C.F.R. 101.60 (regulating “sugars” claims together with “calorie” claims as “nutrient content claims for the calorie content of foods”). While the nexus between sugars and weight loss/control claims that historically has been recognized by FDA has focused on the calorie reductions achieved through the displacement of sugars in food formulations, this was premised on the false assumption that weight loss diets are inherently calorie-restricted diets. FDA policy in this regard does not account for the connection between sugar restriction and weight loss that depends on controlling blood sugar levels rather than calories, which is the basis for the low carbohydrate diets in which Carbolite® foods are commonly used.

The 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 as part of the Nutrition Labeling and Education Act of 1990 (NLEA). During that time, agency policy objectives emphasized the promotion of low fat diets through the standards adopted for nutrition labeling and nutrient content claims. Only a limited range of issues were considered with respect to carbohydrate consumption, and these emphasized the promotion of increased consumption of complex carbohydrates and reduced consumption of sugars across the general population. At no time did FDA consider the food labeling issues presented by the low carbohydrate diets that are popular now, or draw conclusions that are inconsistent with the established use of the Carbolite® brand name. Notably, 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, (*see* 21 C.F.R. 101.80), 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.

In the preamble to the proposed nutrient content claim regulations implementing the NLEA, FDA declined to define “high” and “source” claims for “total carbohydrate” because such claims could not reliably convey meaningful information to consumers seeking either to increase complex carbohydrates or decrease sugars in the diet in accordance with general dietary guidance.

“[D]ietary 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 ambiguous in that it does not allow for the distinction between high levels of complex carbohydrates and high levels of sugars. Furthermore, the agency does not believe that allowing more specific claims relative to levels of carbohydrate in foods, such as ‘high in complex carbohydrates,’ can be supported based on recommendations provided in the major consensus reports concerning complex carbohydrates and sugars intake because quantitative recommendations for these nutrients are not provided. [Additionally,] . . . [t]he inclusion of complex carbohydrates and sugars within the mandatory nutrition label may be misleading to consumers because it may suggest that these nutrients have greater public health significance than has been established by existing diet and health studies. “

56 Fed. Reg. 60421, 60444 (November 27, 1991).

FDA regulations took no account of the need for low carbohydrate dieters to distinguish those carbohydrates affecting blood sugar (i.e., *net effective carbs*) from other carbohydrates. The relevant metabolic distinction is reflected only in FDA’s decision to define “sugar alcohols” separately from “sugars.” 21 C.F.R. 101.9(c)(6)(ii)-(iii). As discussed above, FDA’s specific rationale for making this distinction was to allow foods sweetened with sugar alcohols to qualify for “sugar free” (i.e., “zero sugar”) claims, including for use in sugar-controlled diabetic diets. The proposed use of expressed sugar content claims as benchmarks defining the Carbolite® brand name is founded on the same rationale, and is thus consistent with existing FDA policy.

### **3. Reduction in *Sugar Carbs* and *Net Effective Carbs***

While Carbolite® foods are formulated with sugar alcohols in a manner that qualifies all such foods to bear the “zero sugar” or “reduced sugar” nutrient content claims, Carbolite® formulations are reduced not only in “sugars,” (i.e., *sugar carbs*), but invariably also in *net effective carbs*. Dieters rely on information concerning the *sugar*

*carb* and *net effective carb* content of Carbolite® foods to incorporate these foods appropriately into low carbohydrate diets.

As a result of the strategy used by Carbolite® in the selection of food-types and sweeteners/blends used for foods that ultimately are qualified to bear the Carbolite® brand name, *sugar carbs* are virtually absent or dramatically reduced in the finished foods compared to conventional food counterparts. The reduction in *sugar carbs* yields a corresponding reduction in the overall level of *net effective carbs*. While the extent of the reduction in net effective carb levels varies with the specific food product, the reduction consistently offers a substantial benefit to low carbohydrate dieters over conventional foods. For Carbolite® brand foods to compete successfully in the low carbohydrate food market, it is essential that the reductions made in *sugar carbs* to qualify for “zero sugar” and “reduced sugar” claims translate also into significantly lower levels of *net effective carbs* compared with conventional foods.

The accompanying table and supporting product labeling in Appendix E compares the sugar carb and net effective carb levels of Carbolite® foods with the reference conventional food market leader. 21 C.F.R. 101.13(j)(1)(ii)(A). These data establish that Carbolite® foods are, in fact, lower in *sugar carbs* and *net effective carbs* than reference foods. These data support the use of the “Carbo-” term incorporated in the Carbolite® brand name, to characterize Carbolite® foods as foods that are “reduced in sugar” (encompassing foods labeled as “reduced sugar” and “zero sugar”), and correspondingly also in those carbohydrates that are important to low carbohydrate dieters.

#### **4. Qualifying Information in Labeling for Carbolite® Foods**

As discussed above, the Carbolite® brand name is presented in the context of labeling which includes disclosures and qualifying statements making the intended meaning of the Carbolite® name and intended conditions of use transparent to consumers. This labeling includes nutrition information concerning the carbohydrate content of Carbolite® foods, including in the forms of “zero sugar” and “reduced sugar” claims, Nutrition Facts, and dietary guidance. In addition, current labeling may also include a “Carbohydrate Facts” box which highlights *net effective carb* information, which is particularly useful to low carbohydrate dieters.

Under the petitioned conditions of use, the Carbohydrate Facts box and *net effective carbs* terminology would continue to be permitted for Carbolite® foods. In addition, Carbolite® proposes that the term *sugar carbs* be permitted in labeling to characterize the fraction of *net effective carbs* that are contributed by “sugars,” in the context of substantiated dietary guidance-type claims of the kind proposed in the “model claim” proposed above.

Accordingly, the “Carbo-“ term in the Carbolite® brand name accurately conveys the nature of the nutritional modification made to Carbolite® foods compared to conventional foods, and provides information that is meaningful to low carbohydrate dieters, signaling the fully substantiated connection between Carbolite® foods and low carbohydrate diets in the context of labeling.

#### **B. “Lite” Term in Carbolite® Brand Name**

The use of “lite” embedded within the Carbolite® brand name is truthful, nonmisleading, and fully consistent with the applicable FD&C Act requirements and public policy objectives.

## 1. Carbolite® is Novel Term

The Carbolite® brand name constitutes a novel term with no independent prior history of use, and as such, is distinguishable from all expressed and implied nutrient content claims that have been defined in existing FDA regulations. In no case does the labeling for Carbolite® foods bear the unqualified “lite”/“light” claim, which is authorized only for foods that are reduced in calories or fat. 21 C.F.R. 101.56.

The use of “lite” in the Carbolite® brand name is fully integrated and inseparable from the modifying prefix, “Carbo-.” The brand name thus creates a distinctive context in which the “lite” concept is tied directly to the “carbohydrate” composition of the labeled food product. In addition, the accompanying labeling anchors the Carbolite® brand name with expressed nutrient content claims for sugars (e.g., “zero sugar” or “reduced sugar”). This approach is consistent with the proposal offered by the National Food Processors Association (NFPA) in its 1994 Citizen Petition seeking reforms of FDA policy on First Amendment grounds. That petition proposed amendments to FDA regulations authorizing the use of synonyms and implied nutrient content claims that are not defined in FDA regulations but are reasonably understood by consumers to have the same meaning as a defined term. The NFPA proposal would require such claims to be “anchored” through the use of the corresponding defined term in product labeling. *See* 1994 NFPA Citizen Petition to FDA on Health Claims and Nutrient Content Claims Policy [Docket No. 94P-0390].<sup>1</sup> This anchored claim approach

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<sup>1</sup> FDA proposed narrow regulations in partial response to the NFPA petition that would amend regulations to permit the use of “anchored” synonyms that have not been defined by FDA regulation, but would require the defined term to be used immediately adjacent to the anchored claim, and would prohibit claims modifying defined terms (e.g., “source”). 60 Fed. Reg. 66206 (December 21, 1995). Industry comments have objected

is consistent with the statutory requirements governing “light”/“lite” claims, which are confined to a simple antideception standard. The Act authorizes the Secretary to define “light”/“lite” except where “the Secretary finds that the use of any such term would be misleading.” NLEA Section 3(b)(1)(A)(iii).

## **2. “Light”/“Lite” and Weight Loss/Control Diets**

The legislative history makes clear that the “light”/“lite” regulation was intended to counter a defined pattern of consumer deception that had emerged as a result of inconsistent uses of the term. There was no intent to place rigid or undue restrictions on the use of the “light”/“lite” term, but rather only to authorize the claim in a manner that would ensure the claim offered genuine informational value to consumers, specifically including weight loss/control dieters.

The House report accompanying the NLEA legislation characterizes “light”/“lite” as an implied nutrient content claim “which implies that the product is low in some nutrient (typically calories or fat).” H. Rep. 101-538, 101st Cong. 2d Sess. at 19 (June 13, 1990). The Floor Manager’s Statement accompanying the legislation in the Senate includes specific discussion supporting the notion that “light”/“lite” claims were

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to the FDA restrictions on the ground they are insufficiently responsive to the agency’s obligations under the First Amendment.

In the July 9, 2002 letter from NFPA, CEO, John Cady, to FDA Chief Counsel, Daniel E. Troy, NFPA emphasized the industry’s objections to the FDA proposal and the need to take more aggressive actions to conform with the First Amendment. NFPA objected to the burdensome restrictions of the FDA proposal, arguing that the proposal failed to provide the relief requested even for claims specifically mentioned in the NFPA petition (e.g., “great source of calcium”). NFPA emphasized that “in recent enforcement actions, FDA has continued to maintain an expansive interpretation of its authority to regulate nutrient content claims, strictly enforcing current policy prohibiting undefined synonyms and implied claims in ways that plainly violate the First Amendment.”

broadly conceptualized as a means by which foods suitable for weight loss control diets could be identified for consumers.

The following colloquy appears in the record between Senator DeConcini and Floor Manager, Senator Metzenbaum:

Metzenbaum: “[T]he bill does not specify how the term ‘light’ should be defined or how the Secretary should permit the term to be used. However, the bill gives the Secretary broad authority to develop an appropriate definition so the Secretary certainly could consider permitting the term ‘light’ to be used in the manner you describe.”

DeConcini: “When seeking to define ‘light,’ would it be within the authority of the Secretary to consider, in addition to comparative claims, permitting the use of ‘light’ on foods, such as entrees, meals, and dinners which consumers find useful in the reduction or maintenance of body weight? Entrees, meals and dinners which make significant nutrient contributions and are prepared with ingredients that are inherently low in calories or ingredients selected for their low calorie content should be permitted to use the term light.”

Metzenbaum: “Yes, for the reasons I just described, the Secretary could consider permitting the term to be used in the manner you describe. After receiving a wide range of comments and recommendations, the Secretary would decide on an appropriate definition.”

DeConcini: “I recognize that there have been past abuses in regard to light products and that this bill seeks to stop those abuses. However, it would seem to me that we should not make the definition for light so narrow and rigid that few products would be able to comply with it. Consumers have become more and more knowledgeable about the importance of diet and health, and it would be unfortunate if they were denied an effective tool in helping to identify foods which are useful in reducing weight while also making a significant positive nutrient contribution.”

Cong. Rec. S16607, S16608-S16608 (October 24, 1990) (emphases added).

In the preamble to the proposed regulations implementing the NLEA, FDA also recognized the association consumers make between “light”/“lite” claims and calorie restricted diets.

“[S]ection 3(b)(1)(A)(iii)(III) [of the NLEA] instruct[ed] the agency to define the term ‘light’ or ‘lite.’ The term ‘light,’ as it has been used for a number of years, connotes a wide variety of meanings such as low or reduced calorie; reduced in fat, sugar, or sodium; light in weight, texture, or color; and thin or less viscous. However, surveys conducted in 1982 and early 1990 found that consumers (70 percent in 1982 and 69 percent in 1990) believe that the term “light” means that the caloric level has been altered in some manner.”

56 Fed. Reg. 60421, 60449 (November 27, 1991) (emphases added).

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“Because a majority of consumers associate ‘light’ with a reduction in calories even though there are other meanings for the term, the potential for misuse of the term is created. . . . Although FDA currently has no regulations governing the use of ‘light,’ the agency believes that its definition should be based primarily on consumers’ perception that the word ‘light’ means ‘reduced’ in calories. Therefore, the agency is proposing in section 101.56(b)(1) that the terms ‘light’ or ‘lite’ may be used without further qualification to describe a food provided that the food has been specifically formulated or processed to reduce its calorie content by 33½ percent or more from the reference food that it resembles and for which it substitutes. . . . Because manufacturers of high fat products, such as sour cream and egg nog, have petitioned FDA to use the term ‘light’ to describe the altered versions of their products, and because other normally high fat products, such as cheese foods, are currently using the term ‘light,’ the agency believes that it is necessary to establish criteria for use of the word ‘light’ on altered products that substitute for foods that normally contain relatively high amounts of fat. The agency believes, however, that it would be misleading to permit the term ‘light’ to be used on a product that normally contains relatively high levels of fat and in which the fat has been reduced but not the calories. Therefore, FDA is proposing that for a food in which fat contributes 50 percent or more of the calories to bear the term ‘light,’ it must be reduced

both in calories and for fat, to bear the claim ‘reduced’ (i.e., 33⅓ and 50 percent respectively). . . . [A] ‘light’ claim is really two ‘reduced’ claims . . . .”

56 Fed. Reg. 60421, 60450 (November 27, 1991) (emphases added); *see also* 58 Fed. Reg. 2302, 2352-53 (final regulation accepting evidence that “light” may independently refer to either calorie or fat reduction).

It bears considerable emphasis here, that FDA’s core concept in defining “light”/“lite” was linked to weight loss/control diets involving “reduced calorie” foods. In the context of historical FDA policy, this concept situates “light”/“lite” claims together with reduced sugar claims. As discussed above, sugar content claims historically have been regulated as calorie claims for weight loss control products. In fact, even under current FDA rules, sugar content claims are treated as claims relating to the reduction of calories in food. *See* 21 C.F.R. 101.60.

### 3. “Light Sugar”

Notably, the established regulatory history concerning sugar content claims appears to have stood as an obstacle to FDA in finding a sufficient policy rationale to justify “light”/“lite” claims for “sugar” under the NLEA. In the preamble to the final regulations on “light”/“lite” claims, FDA considered public comments proposing that FDA authorize “light sugar” claims.

“[N]one of the comments provided a rationale for why ‘light sugar’ should be defined. The agency has reviewed these comments and is not convinced that there is sufficient reason to provide a definition for this term. . . . [A]lthough the agency has not defined ‘less added sugar,’ the term ‘less sugar’ could be used to communicate changes in the amount of sugar in the food of the sort that could be communicated if the agency adopted the suggested definition for ‘light sugar.’ However, lacking an adequate justification for the term ‘light sugar,’ the agency is not convinced that such a definition should be established. Accordingly, the agency is not providing for a definition for this term.”

58 Fed. Reg. 2302, 2359 (January 6, 1993).

The scope of issues considered by FDA concerning “light”/“lite” claims for sugar were confined to those arising within the historical construct linking sugar reduction to calorie reduction. Since the FDA definition for “light”/“lite,” by its very nature, is focused on reduced calorie foods useful for weight loss/control diets, and the FDA policy on calorie claims historically has subsumed reduced sugar claims, FDA apparently could discern no context in which “light”/“lite” claims for sugar would provide meaningful information to consumers that would not already be communicated through unqualified “light”/“lite” claims and “reduced sugar” claims.

In considering “light sugar” claims, the link between reduced sugar foods and weight loss/control diets was understood by FDA as being mediated through calorie restriction. FDA was not presented with the alternative construct that forms the basis for low carbohydrate weight loss diets, which restrict only *net effective carbs*, and calorie restriction has no relevance. Had the issues presented by low carbohydrate diets been considered, the unique informational value of “light sugar” claims would have been exposed and distinguished from the “light”/“lite” definition ultimately adopted. In view of the popularity of low carbohydrate weight loss diets currently, FDA may wish to adopt regulations specifically authorizing “light sugar” claims for foods formulated for these diets. However, the absence of such a regulation presents no obstacle to the approval of the Carbolite® brand name now, since the expressed sugar content claims that serve to define the term are appropriate and effective in ensuring the Carbolite® brand name is used in accordance with all legal requirements.

#### 4. Context of “Light”/“Lite”

Current FDA regulations recognize that the meaning of “light”/“lite” is dependent on the context, and authorize qualified “light”/“lite” claims to characterize the level of sodium in food. Notably, in an abbreviated fashion, the “Carbolite®” brand name functions in a manner that is closely analogous to “lite in sodium,” which is specifically authorized under FDA regulations, and conceivably could be collapsed to such a brand name as “SodiumLite.” 21 C.F.R. 101.56(d)(2). The importance of context also is reflected in FDA rules authorizing “light”/“lite” claims to describe physical and organoleptic attributes of food (e.g., “light in color” and “light in texture”). 21 C.F.R. 101.56(e).

FDA regulations for restaurant foods recognize that the potential meanings for “light”/“lite” are diverse and that companies can rely on qualifying information to communicate the meaning intended. This is consistent with First Amendment principles. FDA regulations provide, for example, that companies may use “a term such as ‘lite fare’” provided it is “followed by an asterisk referring to a note that makes clear that . . . [the term] means smaller portion sizes than normal; or an item bearing a symbol referring to a note that makes clear that this item meets the criteria for . . . dietary guidance”. 21 C.F.R. 101.13(q)(3)(iii). In similar fashion, the Carbolite® brand name functions to signal to consumers that the labeled foods are appropriate for low carbohydrate weight loss diets. The substantive meaning of the Carbolite® brand name is reinforced by the qualifying information provided in the context of the entire food label. Under the NLEA framework, “light”/“lite” claims constitute “implied” rather than “expressed” nutrient content claims. While FDA regulations define unqualified “light”/“lite” claims, as a

general matter, FDA policy recognizes that implied claims by their very nature derive meaning from the specific context presented. *See* 21. C.F.R. 101.65.

#### **5. Established Conditions of Use**

FDA regulations explicitly recognize that the meaning of “light”/“lite” can also be determined from the established conditions of use, and on that basis has authorized the claim as part of the statement of identity characterizing the basic nature of food products (e.g., “light brown sugar”). 21 C.F.R. 101.56(f). These regulations specify that such labeling is appropriate where the “manufacturer can demonstrate that the word ‘light’ has been associated, through common use, with a particular food . . . .” This standard supports the use of “lite” as part of the Carbolite® brand name, which is associated through common use with “zero sugar” and “reduced sugar” foods that are formulated as alternatives to conventional foods for low carbohydrate weight loss diets.

The Carbolite® brand name is completely consistent with the statutory standards for the “light”/“lite” claim, and established FDA policy positioning the claim for foods promoting weight loss/control. The name builds upon this policy to embrace the “light sugar” concept (i.e., “reduced sugar”) in connection with low carbohydrate diets for weight loss through the distinctive “Carbolite®” term, and the context in which the Carbolite® brand name is presented in product labeling. Just as the connection consumers historically have made between “light”/“lite” and weight loss/control has provided the rationale for FDA’s current policy defining unqualified “light”/“lite” claims to mean “reduced calorie,” on a parallel basis, the Carbolite® brand name to mean “reduced sugar” (and encompassing foods qualifying as “zero sugar”) is justified in the context of low carbohydrate diets. Authorizing the Carbolite® brand name supports the specialized informational needs of low carbohydrate dieters.

Under the conditions of use proposed in this petition, foods bearing the Carbolite® brand name would be labeled with a dietary guidance statement concerning the use of these products in low carbohydrate diets, which specifically includes the following disclaimer making clear that Carbolite® foods do not necessarily qualify as “light”/“lite” under FDA regulations.

**Model Claim:** *“Carbolite® products are not necessarily ‘light’ or ‘low’ in calories or fat. See Nutrition Facts for information on carbohydrate, fat, and calories.”*

**C. Foods Bearing the Carbolite® Brand Name Conform with FDA Requirements for “Zero Sugar” and “Reduced Sugar”**

Under the proposed conditions of use, the Carbolite® brand name is consistent with the terms “zero sugar,” as defined under 21 C.F.R. 101.60(c)(1), or “reduced sugar” under 21 C.F.R. 101.60(c)(5).

**1. “Zero Sugar” Products**

Under 21 C.F.R. 101.60(c)(1), a food may be labeled as “zero sugar” if three conditions are satisfied: (i) the food contains less than 0.5 g of sugar as defined in 21 C.F.R. 101.9(c)(6)(ii); (ii) the food does not contain any ingredient that is customarily understood to have sugar; and (iii) the food is labeled as “low calorie” or “reduced calorie” as provided in 21 C.F.R. 101.60(b)(2), (b)(3), (b)(4), or (b)(5), or is labeled as “not a low calorie food.” Appendix F shows the results of tests on Carbolite® Inc. foods establishing that these foods satisfy the first two conditions to be labeled as “zero sugar.” Appendix G describes the methods used to test the sugar and calorie content of these foods, which were in accordance with the Association of Official Analytical Chemists International (AOAC) methods.

As set forth above in the proposed Carbolite® labeling, all foods in this category will be labeled with the Carbolite® brand name, the nutrition facts, and the romance copy. In addition, these foods will be labeled as “zero sugar” or one of the synonyms provided in 21 C.F.R. 101.60(c)(1) or with “zero *sugar carbs*” or “0 *sugar carbs*.”<sup>2</sup> Finally, the subset of “zero sugar” foods that satisfy the criteria to be labeled as “low calorie” or “reduced calorie” will be labeled as such; all other “zero calorie” foods will be labeled as “not a low calorie food.” This labeling is consistent with the labeling required for zero sugar foods under 21 C.F.R. 101.60(c)(1) and clearly indicates to consumers that these are zero sugar products for use as part of a controlled sugar diet.

## **2. “Reduced Sugar” Products**

Under 21 C.F.R. 101.60(c)(5), a food may be labeled as “reduced sugar” if: (i) the food contains at least 25 percent less sugar than an appropriate reference food; (ii) the label identifies the reference food and the percent difference in sugar content; and (iii) the label includes quantitative information comparing the amount of sugar in the food to the amount of sugar in the reference food. For purposes of the proposed Carbolite® labeling, Carbolite® Inc. has compared the sugar content of its “reduced sugar” foods to the reference market leader in conformance with the market basket approach required for “light”/“lite” claims under 21 C.F.R. 101.13(j)(ii)(A). Appendix F shows the results of these tests. Appendix G describes the methodology used for these tests, which were in accordance with AOAC methods.

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<sup>2</sup> The label “zero *sugar carbs*”/“0 *sugar carbs*” will not confuse consumers into believing that the product has zero carbohydrates because of the explanatory language in the Nutrition Facts and the romance copy.

All foods in this category will be labeled with the Carbolite® brand name, the Nutrition Facts, and the romance copy as set forth above in the proposed Carbolite® labeling. In addition, these foods will be labeled as “reduced sugar” or one of the synonyms provided in 21 C.F.R. 101.60(c)(5). A percentage comparison of sugar content with the reference food will appear immediately adjacent to the “reduced sugar” claim. In addition, the information panel of the package will include a quantitative comparison of the sugar content in the reference food. This labeling conforms to that required by 21 C.F.R. 101.60(c)(5) and clearly indicates to consumers that these products are reduced sugar products.

**D. The Carbolite® Brand Name Constitutes Commercial Speech Protected by the First Amendment**

Approval of the Carbolite® brand name would uphold the agency’s obligations under the First Amendment to avoid undue restriction of commercial speech. It is well established that trademarks convey valuable information and constitute commercial speech that is protected by the First Amendment. *See Bad Frog Brewery, Inc. v. New York State Liquor Authority*, 134 F.3d 87, 96-97 (2d Cir. 1998).

So long as commercial speech concerns a lawful activity and is not misleading, commercial expression may not be restricted except where: (1) the government has a substantial interest in restricting the speech; (2) the regulation “directly advances” the government interest, and (3) the regulation “is not more extensive than necessary to serve that interest.” *Central Hudson Gas & Elec. Co. v. Public Serv. Comm’n*, 447 U.S. 557, 564 (1980). No restriction on commercial speech can be sustained under this standard unless the government “demonstrate[s] that the harms it

recites are real and that [the speech restriction] will alleviate them to a material degree.” Edenfield v. Fane, 507 U.S. 761, 770-71 (1993).

A limit on commercial speech is *per se* unreasonable if a less restrictive approach, such as requiring a clarifying disclosure or disclaimer, would suffice to remedy established deception. *Pearson v. Shalala*, 164 F.3d 650, 657-58, *reh'g denied* 172 F.3d 72 (D.C. Cir. 1999). In *Pearson*, the court invalidated an FDA regulation that required pre-approval of health claims for dietary supplements because FDA had failed to consider the alternative of allowing disclaimers. *Id.* Applying the *Central Hudson* test, the court found that FDA has a substantial interest in ensuring the accuracy of health claims to protect the health, safety and welfare of consumers and that requiring pre-approval of health claims for dietary supplements may directly advance this government interest. *Id.* at 655-56. However, the court found fault with FDA’s approach of banning health claims outright rather than taking the less restrictive approach of allowing for disclaimers. *Id.* at 657-58. The “government must, where possible, regulate misleading commercial speech by requiring disclaimers rather than imposing an outright ban.” *Id.* at 657; *see also Bad Frog Brewery*, 134 F.3d at 101-02 (striking down ban on use of trademark on liquor bottle when other, less stringent measures could serve the state interest of protecting minors).

Similarly, a trademark may not be excised where a less drastic measure, such as the addition of qualifying language, would prevent misleading consumers. *Jacob Siegel v. FTC*, 327 U.S. 608, 611-13 (1946); *FTC v. Royal Milling Co.*, 288 U.S. 212, 217 (1933). In *Royal Milling*, the Court held the FTC impermissibly excised the “Royal Milling” mark from a flour producer and distributor that did not in fact grind the wheat.

*Royal Milling*, 288 U.S. at 217. The Court reasoned that it would be less drastic, but equally effective, to include a disclaimer on the package that Royal Milling Co. does not grind the wheat. *Id.*

FDA has noted its intent to comply with this policy in the context of the continued use of existing brand names on reformulated drugs:

It is the policy of the Food and Drug Administration, in accordance with principles laid down in the courts, to require excision of a brand name only where nothing short of excision would eliminate the possibility of deception...

39 Fed. Reg. 11,298, 11,298 (Mar. 27, 1974) (citing *Royal Milling*).<sup>3</sup> Similarly, FDA regulations regarding nutrient content claims for food generally prefer disclaimers over the outright ban of these claims. *See. e.g.*, 21 C.F.R. 101.56 (allowing “light” claims with disclaimers), 101.60 (allowing sugar content claims with disclaimers), 101.61 (allowing sodium content claims with disclaimers). Thus, an outright prohibition on the use of the Carbolite® brand name, when additional disclosures would suffice to satisfy any FDA concerns about the trademark, would violate the First Amendment and would present serious concerns under policies related to trademark excision.

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<sup>3</sup> In the preamble to a final rule regarding dietary supplement claims, FDA noted that this proposed rule is no longer in effect because it was withdrawn in 1991 in an effort by FDA to reduce administrative backlog. 65 Fed. Reg. 1000, 1022 (January 6, 2000). However, at that time, FDA stated the withdrawal was “not intended to affect whatever utility the preamble statements may currently have as indications of FDA’s position on a matter at the time of the proposal was published,” and should not be viewed as an indication of FDA’s position on the issue at the time of the withdrawal. 56 Fed. Reg. 42,668 (August 28, 1991). Moreover, the final rule on dietary supplement claims follows the statutory mandate of preferring disclaimers over the outright ban of brand names. 65 Fed. Reg. at 1001.

**E. Prohibiting the Use of the Carbolite® Brand Name Would Constitute a Taking, Without Just Compensation, Under the Fifth Amendment**

A prohibition on the use of the Carbolite® brand name would constitute an unconstitutional taking of private property under the Takings Clause of the Fifth Amendment. Under the Takings Clause, the government may not take private property for public use without just compensation. U.S. Const. Amend. V. The taking of private property can occur through government regulation that goes “too far.” *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1014 (1992). A trademark is a valuable property asset of a business, *Friedman*, 440 U.S. at 1, n.11 (1979), the deprivation of which may constitute a taking under the Fifth Amendment. *Maltina Corp. v. Cawy Bottling Co.*, 462 F.2d 1021, 1027 (forced dissolution of a company constitutes Fifth Amendment taking of trademark); *see also Rucklehaus v. Monsanto*, 467 U.S. 986, 1003-04 (1984) (trade secret is property right protected by Fifth Amendment). [In order to determine whether a regulation constitutes a taking, the following factors should be considered: (1) the character of the government action; (2) the extent to which the regulation interferes with distinct, investment backed expectations; and (3) the economic impact of the regulation. *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104, 124 (1977).]

The Carbolite® brand name has been used for three years and is one of Carbolite® Inc.’s most valuable and important business assets. Carbolite® Inc. is a small company whose sole business is the manufacture and sale of “zero sugar” and “reduced sugar” for low carbohydrate weight loss and sugar-controlled diets. Carbolite® has established substantial name recognition and good will in the marketplace associated with the Carbolite® brand name. The Carbolite® name has come to represent high-quality

food products for low carbohydrate diets. Prohibiting the use of the Carbolite® brand name would be tantamount to putting Carbolite® Inc. out of business and would constitute a taking of property that could not readily be recompensed. This is especially true because, as discussed above, an outright prohibition on the use of the Carbolite® name could not be justified under the First Amendment.

### **III. ENVIRONMENTAL IMPACT**

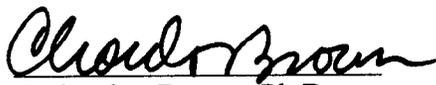
The issuance of regulation by FDA in response to a nutrient content claim petition, under 21 C.F.R. 101.69, is one of the classes of actions listed in FDA regulations as categorically excluded and, therefore, does not require the preparation of an Environmental Assessment or an Environmental Impact Statement. 21 C.F.R. 25.32(p).

### **IV. CONCLUSION AND CERTIFICATION**

For the foregoing reasons, Carbolite® Inc. requests that FDA approve the proposed Carbolite® labeling. On behalf of Carbolite® Inc., I hereby certify that, to the best of my knowledge, this petition is a representative and balanced submission that includes unfavorable information as well as favorable information known to me to be pertinent to the evaluation of this petition.

Respectfully submitted,

**CARBOLITE® FOODS, INC.**

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