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

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

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VIA ELECTRONIC AND MAIL DELIVERY

Dockets Management Branch
(HFA - 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD
fdadockets@oc.fda.gov

Re: Docket No. 02P-0462 - Petition for the Use of an Implied Nutrient Content Claim in the Brand Name Carbolite® –
PETITIONER'S RESPONSE TO PUBLIC COMMENTS

TO WHOM IT MAY CONCERN:

The undersigned, C. Gordon Brown, Ph.D., Vice President – Research and Quality Systems, submits this Response to Public Comments on behalf of the Petitioner, Carbolite Foods, Inc. ("Carbolite®"). In accordance with section 403(r)(4) of the Federal Food Drug and Cosmetic Act ("FD&C Act"), and the First Amendment of the U.S. Constitution, the company submitted the above referenced brand name petition under 21 C.F.R. 101.69(o) to ensure that the company brand name, "Carbolite®," may continue to be used for its line of "zero sugar" and "reduced sugar" food products marketed exclusively for use in low carbohydrate diet regimes restricting net effective carbohydrate intake (i.e., sugars and starches).

Carbolite® food products are formulated to eliminate or substantially reduce the level of "sugars" per reference amount customarily consumed (RACC) compared with the conventional food alternatives for which Carbolite® foods may be substituted in the diet. The significant

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reduction in sugars yields a correspondingly significant reduction in net effective carbohydrate compared to reference conventional foods. The Carbolite® product line is composed of foods qualifying either as "zero sugar" or "reduced sugar." In the reduced sugar foods, sugars are reduced by at least 95 percent compared with reference foods. Carbolite® products uniformly supply no more than 4 grams net effective carbohydrate per RACC. The grams net effective carbohydrate contained in a food constitutes the grams of carbohydrate having a significant effect on blood sugar levels and insulin response, and represent the subclass of total carbohydrates that is meaningful to individuals following low carbohydrate dietary regimes. Under the conditions of use set forth in the petition, the Carbolite® brand name would be permitted for use only for foods that qualify as "zero sugar" or "reduced sugar" and are marketed exclusively for use in low carbohydrate diets restricting net effective carbohydrate intake.

The Carbolite® petition establishes that, under the specified conditions of use, the Carbolite® brand name is accurate, substantiated, and in full conformance with the FD&C Act. The petition further establishes that the company's continued use of the Carbolite® brand name under these conditions of use is protected under the First Amendment of the U.S. Constitution. FDA lacks authority to restrict the company's use of its brand name except to the extent specific limitations are needed to alleviate a genuine harm that is established from evidence. Restrictions based on speculation or conjecture cannot be sustained. Under the First Amendment, no restriction can be sustained 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). Restrictions are deemed unreasonable under this standard and cannot be sustained if a less restrictive approach, such as requiring a clarifying disclosure, would be sufficient to remedy deception. Pearson v. Shalala, 164 F.3d 650, 657-58, reh'g denied 172 F.3d 72 (D.C. Cir. 1999). (See Carbolite® Petition at pages 25-27).

The Petitioner has reviewed the public comments filed in Docket No. 02P-0462 opposing the Carbolite® brand name petition and finds them to be groundless. Petitioner offers this response to establish for the record that the public comments provide no basis upon which FDA can lawfully decline to approve the Carbolite® petition.

A. Allegations Concerning Consumer Deception are Unfounded and Speculative

Comments objecting to the Carbolite® brand name were submitted by Universal Nutrition, a Carbolite® competitor which the company has recently sued for trademark infringement of its Carbolite® brand name. (See pages 6-7 below). While this lawsuit has no relevance to FDA's approval of the Carbolite® petition, Universal Nutrition's objections to the Carbolite® brand name are baseless and seem motivated to advance that company's particular competitive and litigation interests.

Universal Nutrition objects to the Carbolite® brand name asserting that, under the conditions of use set forth in the petition, the "Carbo" prefix embedded in the Carbolite® brand name may confuse or mislead consumers by implying that "sugar" and "carbohydrate" are interchangeable terms, allegedly obscuring the fact that sugar free and reduced sugar foods may not be reduced in "total carbohydrate" content. (See Universal Nutrition comments at pages 5-6; see also comments of C. Harvey and H. Katz mistakenly suggesting that Carbolite® could be used deceptively for foods that are not "low" in total carbohydrate). Under FDA rules, "total carbohydrate" is defined to include sugar alcohols, which are used in place of "sugars" to sweeten Carbolite® foods. 21 C.F.R. 101.9(c)(6). The substantial reductions in net effective carbohydrate which are important and meaningful to consumers following low carbohydrate diet regimes are not communicated through the declaration of "total carbohydrate" that is required under FDA regulations. Id. For this reason, the conditions of use specified in the petition provide that the Carbolite® brand name be accompanied by dietary guidance labeling concerning the use of Carbolite® products for "sugar-controlled" diets limiting net effective carbohydrate intake. (See italicized statement at page 5 below).

The argument that the "Carbo" reference in the Carbolite® brand name should be treated as an implied nutrient content claim exclusively for total carbohydrates is groundless. First, there is no basis for assuming that "Carbo" inherently means "total carbohydrate." Notably, "Carbo" has a long established history of use in the food industry to refer to sugars rather than total carbohydrates. For example, the "Carbotrol®" brand name has been in use since 1979 for

unsweetened and sugar free fruit and dessert products widely marketed for institutional use. (See Reg. No. 1157489; Appln. No. 76/398,525).

Second, there is no evidence that the Carbolite® brand name, which already is well established in the low carbohydrate foods market, is responsible for any pattern of consumer deception concerning the nature or level of carbohydrates contained in Carbolite® foods. To the contrary, the market success of Carbolite® foods among consumers following low carbohydrate diet regimes in which net effective carbohydrate intake – and not total carbohydrate intake is important – provides solid evidence that the brand name and accompanying product labeling is meaningful and effective in reaching those consumers for which Carbolite® products are intended and marketed exclusively.

Third, there is no basis for comments suggesting that consumers would be better informed if "light carbohydrate" claims were defined by FDA with exclusive reference to the total carbohydrate content of food than with the Carbolite® approach, which anchors the meaning with expressed "zero sugar" and "reduced sugar" claims. These comments fail to account for the substantial nutrition policy concerns that have motivated FDA's current ban on nutrient content claims characterizing the level of "total carbohydrate" in food. As discussed at pages 11-12 of the Carbolite® petition, this ban is based on FDA's determination that consumers seeking to modify their intake of carbohydrates to achieve dietary goals must necessarily focus separately on the carbohydrate subclasses for which meaningful dietary guidance is established (e.g., "complex carbohydrate," "dietary fiber," "sugars"). Accordingly, FDA has determined that nutrient content claims concerning particular carbohydrate subclasses can provide meaningful information in relationship to such dietary goals (e.g., "sugar free," "reduced sugar"), whereas claims concerning the aggregate category, "total carbohydrate," are not meaningful in this context, and thus are considered by FDA to be inherently misleading to consumers. (See Carbolite® Petition at 12 (discussing 56 Fed. Reg. 60421, 60444 (November 27, 1991))).

Fourth, the comments objecting to the Carbolite® brand name fail to account for the accompanying label information which provides important context and meaning for the Carbolite® name. The governing statutory and First Amendment standards obligate FDA to evaluate the Carbolite® brand name under the actual conditions of use. The Carbolite® petition sets forth detailed labeling specifications for food products bearing the Carbolite® brand name which ensure that the meaning of the name is clear and unambiguous under the actual conditions of use in which Carbolite® products are marketed to consumers. [1] Specifically, the label of each food product bearing the Carbolite® brand name includes (1) the nutrient content claim, "zero sugar" or "reduced sugar" or synonyms for these terms defined by FDA regulation (21 C.F.R. 101.60(c)); (2) Nutrition Facts setting forth the number of grams of total carbohydrates, and separately, the grams of dietary fiber, sugar alcohols, and sugars; and (3) a dietary guidance statement which discloses the fact that Carbolite® foods are intended for sugar controlled diets and are not necessarily "light" or "low" in calories, fat, or sodium such as the following model statement:

"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."

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[1] The Carbolite® brand name petition requests FDA to authorize the continued use of the Carbolite® brand name as an implied nutrient content claim under 21 C.F.R. 101.69(o), including on the principal display panel, under specified conditions of use. Notably, the "Carbolite®" name already is required to appear on the same food labels that are subject to the petition as part of the company's identity statement. 21 C.F.R. 101.5(a). Section 101.5(a) of FDA rules provides that "the label of a food in packaged form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor," and specified that "the requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, *only by the actual corporate name . . ..*" (Emphasis added.) The petition would have no effect on the current use of the Carbolite® name under this section of FDA regulations.

In addition to these mandatory disclosures, Carbolite® Foods may also be labeled with the "Carbohydrate Facts" panel in current use, which highlights the amount of "net effective carbs" in each product. (See Carbolite® Petition at page 5-6).

B. The Trademark Allegations Are Irrelevant

The comments of Universal Nutrition raise several objections to the Carbolite® brand name based on issues of trademark law which have no relevance to the FDA decision on the Carbolite® petition. As stated above, Carbolite® has sued Universal Nutrition for trademark infringement of the Carbolite® brand name. In that lawsuit, which is pending before the United States District Court for the Southern District of Indiana, Defendant, Universal Nutrition has the opportunity to fully litigate the trademark law issues alleged in its comments to FDA. (See Case No. IPO2-1308-C M/S). In that case, Carbolite® claims that Universal Nutrition's use of the "Carbrite" term for low carbohydrate foods is confusingly similar to the "Carbolite®" trademark, and thus infringes the Carbolite® trademark in violation of the Lanham Act, the federal trademark statute. 15 U.S.C. 1051 et. seq. The issue in that litigation, of whether there is a "likelihood of confusion" between Carbolite® and Carbrite trademarks, has no relevance here. Indeed, the issues for the FDA would be identical had Carbolite® never filed to federally register its trademark. Carbolite® would have common law trademark rights regardless of federal registration of the trademark. Moreover, there is no requirement under the FD&C Act that confines FDA approval of petitions submitted under 21 C.F.R. 101.69(o) to brand names that are federally registered trademarks.

The comments of Universal Nutrition also attempt to obscure the matters before FDA by suggesting that the federal registration status of the Carbolite® brand name is in doubt because of objections that Universal Nutrition has filed with USPTO. These comments mischaracterize the status of the Carbolite® registration and the USPTO proceedings. (See Carbolite® Docket Registration No. 2653620 at http://tarr.uspto.gov/). Universal Nutrition has indicated that it objected to the USPTO granting the Carbolite® trademark. However, subsequently, the USPTO's Trademark Trial and Appeal Board rejected Universal's petition to withdraw the

Carbolite® trademark registration, and only procedural issues concerning whether Universal Nutrition's opposition was filed in a timely manner are currently pending. In any event, the merits of Universal Nutrition's opposition to the Carbolite® registration are being litigated in the pending lawsuit against Universal Nutrition for trademark infringement. Regardless of the outcome of the USPTO proceedings and trademark litigation, these matters have no relevance to the issues before FDA.

The comments of Universal Nutrition mistakenly suggest that Petitioner has misused the "®" symbol in its petition. In fact, these comments do nothing more than identify the November 26, 2002 date upon which the company became legally authorized to use the "®" symbol under the federal trademark statute. 15 U.S.C. 1111. At the time the Carbolite® brand name petition was filed, the "®" authorization was imminent and was scheduled to be authorized well in advance of the January 15, 2003 deadline for the FDA ruling on the petition. The use of the registration symbol in a legal brief under the circumstances presented by the petition is appropriate and to be distinguished from a commercial use by the company in product labeling to designate that the trademark is federally registered. In any case, the use of the "®" symbol in the petition has no relevance under the legal standards governing the FDA decision on the Carbolite® brand name petition.

C. The Allegations of Unfair Advantage Are Groundless

The comments of Universal Nutrition are mistaken in arguing that FDA can deny the Carbolite® petition to promote a "level playing field" for Carbolite® competitors marketing low carbohydrate food products under other brand names. (See also comments of H. Katz). Universal Nutrition's comments also are misinformed in suggesting that, by approving the Carbolite® brand name, FDA would effectively approve "low carb" claims for one company which were prohibited in warning letters issued to other companies. Like Universal Nutrition and other companies in the low carbohydrate foods market, Petitioner modified the labeling for Carbolite® products in response to an FDA warning letter. (See Warning Letter ONPLDS 20-01). Petitioner has responded fully to the issues presented in the FDA warning letter by means

of the petition filed under 21 C.F.R. 101.69(o) and the changes made to product labeling. The product labeling submitted as part of the Carbolite® petition illustrates the labeling changes made to respond to the warning letter (e.g., "0 sugar carbs" claim changed to "0 sugar"). (See Carbolite® Petition, Appendix C). The Carbolite® labeling at issue included no "low carb" claims, however, and such claims thus were not at issue in the FDA warning letter. In contrast, the FDA warning letter issued to Universal Nutrition determined that the company's brand name, "Doctor's Diet Low Carb Bar," constituted an unapproved "low carbohydrate" claim. (See Warning Letter ONPLDS 08-01 (attached)). Universal Nutrition chose to respond to the FDA warning letter by changing its brand name. The company apparently made no attempt to gain FDA approval of its brand name under 21 C.F.R. 101.69(o), even though that procedure was available to the company.

Carbolite® competitors are free to seek FDA approval of implied claims in their own brand names or to petition the agency for regulations authorizing nutrient content claims appropriate for general use in the low carbohydrate foods market (e.g., "light carbohydrate"). See 21 C.F.R. 101.69. The steps Petitioner has taken to exercise its lawful rights under the FD&C Act and First Amendment to seek FDA approval of the Carbolite® brand name result in no unfairness to competitors. The failure of Carbolite® competitors to take advantage of the publicly available petition procedures cannot operate to impede FDA approval of the Carbolite® brand

name petition. Not only is Petitioner entitled to continue to use its Carbolite® brand name under the FD&C Act, but to restrict the company's use of the brand name, as the public comments argue FDA should do, would violate the First Amendment.

Sincerely,

C. Gordon Brown, Ph.D.
Vice President-Research and Quality
Systems - Carbolite® Foods, Inc.

Sarah E. Taylor, J.D., R.D., M.P.H.
COVINGTON & BURLING
1201 Pennsylvania Ave., NW
Washington, DC 20004-2401
Tel: (202)662-5563
Fax: (202)778-5563
email: staylor@cov.com
Counsel to Petitioner - Carbolite® Foods, Inc.

cc: BY FACSIMILE AND EMAIL DELIVERY
Christine Taylor
John Foret
Constance Henry
Office of Nutritional Products, Labeling and Dietary Supplements (HFS-830)
Food and Drug Administration
Department of Health and Human Services
Washington, D.C. 20204

Attachment