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Food and Drug Administration
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PETITION FOR RECONSIDERATION AND STAY OF ACTION

Docket No. 02P-0462

The undersigned, C. Gordon Brown, Ph.D., Vice President - Research and Quality Systems, submits this petition on behalf of Carbolite Foods, Inc. ("Carbolite®") in accordance with 21 C.F.R. 10.33 and 10.35 for reconsideration and stay of the decision of the Food and Drug Administration ("FDA") in Docket No. 02P-0462, including a stay of any further enforcement action with respect to the Warning Letter sent by FDA to Carbolite® in June 2001 regarding use of the Carbolite® brand name.

A. Decision Involved

This petition seeks reconsideration of the January 15, 2003 FDA decision ("Decision") denying the petition submitted by Carbolite® on October 4, 2002 pursuant to section 403(r)(4)(A)(iii) of the Federal Food Drug and Cosmetic Act ("FD&C Act") (21 U.S.C. § 343(r)(4)(A)(iii)) and 21 C.F.R. § 101.69(o), to ensure that Carbolite® may continue to use the company brand name "Carbolite®" for its line of "zero sugar" and "reduced sugar" food products marketed for use in low carbohydrate diet regimes restricting the intake of sugars and starches (i.e., "net effective carbohydrate" intake).

In reaching this decision, FDA failed to adhere to the applicable First Amendment standards confining the agency's authority to restrict commercial speech and, as a result, failed to

respect the right of Carbolite® to continue to use its company brand name together with the qualifying labeling that would remedy any genuine risk of deception the agency could establish. Furthermore, FDA failed to account for the clear limits of agency authority under the First Amendment in its construction of the relevant statutory provisions, including with respect to the agency's argument that "Carbolite®" is inconsistent with the requirements for implied nutrient content claims in a brand name under section 403(r)(2)(A)(i) of the FD&C Act.

In making these determinations, the agency ignores over sixty years of FDA regulations authorizing label statements that address the nexus between sugar and other carbohydrates and the distinctions between their effects on the body, and draws the unsubstantiated conclusion that the Carbolite® brand name, along with the proposed labeling, is incapable of being understood by consumers except as a characterization of the level of total carbohydrates in food. *See* Decision at 4, 6-7. FDA also makes the groundless argument that a brand name petition was not the appropriate vehicle for authorization of Carbolite®'s proposed claim. Rather, FDA claims -- in direct contravention of basic principles of statutory construction -- that the company should instead proceed under the more onerous procedure for petitioning FDA for a new "low carbohydrate" nutrient content claim under section 403(r)(4)(A)(i) of the FD&C Act. The record provides no evidence that restricting the use of the Carbolite® brand name through this kind of burdensome premarket approval procedure is necessary to alleviate a genuine harm established from evidence concerning the petitioned use of the name. Moreover, the agency seems to be suggesting that for one company to make use of an implied nutrient content claim in a brand name, it must first bear the regulatory burden of gaining FDA approval of an expressed nutrient content claim which would be available for general use by the company's competitors. This suggestion exposes the insensitivity of the agency to the market-driven factors which contribute value and meaning to the commercial speech subject to FDA

regulation. Where the regulatory barrier to entry FDA creates is so high that a company cannot afford to employ an accurate, substantiated implied claim in a brand name, the FDA policy amounts to an impermissible ban on commercial speech.

Because FDA failed to evaluate the record in accordance with the proper legal standards, and disregarded the constitutional limits of agency authority to restrict the use of the Carbolite® brand name, FDA's denial of Carbolite®'s petition for an implied nutrient content claim in a brand name is unlawful and cannot stand.

B. Action Requested

Under the First Amendment, the government lacks legal authority to place any restriction on commercial speech except where it proves, based on evidence, that the restriction is necessary to remedy a concrete harm presented by the specific speech at issue. Whatever may be the worthy intentions of the FD&C Act provisions and implementing regulations, they cannot empower the government to enforce restrictions on labeling claims that are accurate and fully substantiated. The First Amendment establishes a firm boundary of protection around each truthful and substantiated expression, and forbids the government from applying statutes and regulations to restrict such commercial speech in a manner that cannot be justified to alleviate a genuine harm attributable to the actual speech at issue. Moreover, where the government establishes its authority to impose restrictions, the First Amendment favors the remedy of further disclosure to the suppression of speech.

Because FDA has no authority to prohibit the use of the Carbolite® brand name without first establishing that such restriction is necessary to prevent concrete harm and that further qualifying language cannot alleviate that harm, Carbolite® now petitions FDA to reconsider Carbolite®'s petition for an implied nutrient content claim in a brand name, and to render a decision that respects the mandates of the First Amendment which defines the limits of

FDA discretion in interpreting its statutory authority to place restrictions on commercial speech under the FD&C Act. A proper evaluation of Carbolite®'s petition under this governing authority must yield a determination to authorize the Carbolite® brand name together with appropriate qualifying labeling to remedy any genuine deception established by FDA.

FDA's decision denying the Carbolite® brand name petition is unsupported by the applicable First Amendment, Administrative Procedure Act ("APA") and FD&C Act law. Accordingly, Carbolite® petitions the agency to stay any enforcement action under that Decision, including any enforcement action under the June 2001 warning letter with respect to use of the Carbolite® brand name, pending reconsideration of Carbolite®'s brand name petition in accordance with governing law.

C. Statement of Grounds

The Carbolite® brand name is a registered trademark owned by Carbolite® Inc. which is used exclusively for the line of "zero sugar" and "reduced sugar" food products marketed by and on behalf of Carbolite® Inc. As stated on the product labeling, these 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"). Net effective carbs encompasses those carbohydrates which are metabolized in a manner that affects blood sugar levels and insulin release, and are comprised of starches and sugars. "Net effective carbs" refers to the same carbohydrates as "fermentable carbohydrates," as that term has been defined under FDA regulations. 21 C.F.R. 101.80. These terms amount to synonyms referring to the aggregate amount of sugars and starches contained in a food, and which would contribute to the overall amount of carbohydrate declared as "total carbohydrate" under the general FDA nutrition labeling regulations that apply to Carbolite® food products. 21 C.F.R. 101.9(c)(6). "Net effective carbs" and "fermentable carbohydrate"

alike are defined to exclude carbohydrates from sugar alcohol and dietary fiber, and are distinguished from the FDA definition of "total carbohydrate" in this way. Under current FDA regulations, "0 fermentable carbohydrate" is authorized for use in food labeling for "sugar free" food products for which the Nutrition Facts box would declare "total carbohydrate" from sugar alcohols. This situation is directly analogous to the declaration of "0 net effective carb" for Carbolite® foods for which the Nutrition Facts box declares total carbohydrate contributed by sugar alcohols. See 21 C.F.R. 101.9(c)(6), 101.80(d).

As described in Carbolite®'s initial October 4, 2002 petition ("Petition"), the Carbolite® brand name appears only on products labeled "zero sugar" and "reduced sugar" in accordance with applicable FDA regulations. The brand name is used in conjunction with a dietary guidance statement which qualifies the use of the Carbolite® brand name by disclosing explicitly that the labeled products are not necessarily "light" or "low" in calories or fat, and references the Nutrition Facts disclosure specifying the levels of "total carbohydrate" and the subclasses, "sugars" and "sugar alcohols," as well as fat and calories disclosed in the mandatory Nutrition Facts Labeling. Under the conditions of use set forth in the petition, Carbolite® products will also be labeled with a "Carbohydrate Facts" box, which replicates the carbohydrate information disclosed in the Nutrition Facts box in a highlighted format which discloses the relationship between these carbohydrate levels and the "net effective carb" (i.e., fermentable carbohydrate) content. In the context of the entire labeling, the petitioned use of the Carbolite® brand name is truthful, substantiated, and not misleading, and entitled to First Amendment protection. "Net effective carb" levels are meaningful to Carbolite® consumers because these carbohydrates, and not "total carbohydrates," are restricted in "low carbohydrate" weight loss diet plans and other dietary regimes.

I. FDA's Ban of the Carbolite® Brand Name Violates the First Amendment

Section 403(r)(4)(A)(iii) of the FD&C Act requires FDA to grant a petition for use of an implied claim in a brand name if the agency finds that such claim is not misleading and is consistent with terms defined by FDA under section 403(r)(2)(A)(i). Despite the full and accurate disclosure of the nutritional composition of food products bearing the Carbolite® brand name, FDA concluded that the Carbolite® brand name is entitled to no First Amendment protection, as a matter of law. FDA relied on the same line of argument that the federal courts repeatedly have rejected from FDA, that is, that the speech in question -- "Carbolite®" in this case -- is "inherently misleading" and thus falls outside the zone of First Amendment protection.

FDA cannot carry the burden of proof necessary to establish its authority to restrict commercial speech when it fails to demonstrate the restriction applied in the specific case is necessary to remedy actual deception established from genuine evidence. In addition, the agency cannot carry its burden when it fails to consider the range of potential qualifications and disclosures that may accompany a claim, and reduces its evaluation to a categorical "pass"/"fail" determination. The government is obligated to consider whether providing more speech in the form of qualifying or explanatory labeling can remedy any genuine risk of deception, before it can establish its authority to ban a claim outright. *Pearson v. Shalala*, 164 F.3d 650, 657 (D.C.Cir. 1999). Moreover, the First Amendment obliges the agency to look beyond the disclaimers offered by the proponent of the claim and to consider sua sponte the potential qualifications that could be added to the proposed labeling to remedy any genuine risk of deception the agency has established to exist. *Id.* at 659.

In its initial evaluation of Carbolite®'s petition, FDA apparently made no attempt even to address the question of the potential for further qualifications of the Carbolite® brand

name, or to establish on the record any basis for concluding, as a matter of fact, that the Carbolite® brand name cannot be qualified to remedy any genuine risk of deception. Furthermore, FDA relied on speculation and conjecture with respect to the meaning of the Carbolite® term to real consumers using the Carbolite® products, rather than on genuine evidence of the kind that is required for the government to carry its burden of proof under the First Amendment. FDA has failed to establish its authority to ban the Carbolite® brand name and is obligated to reconsider its Decision in accordance with the First Amendment standard applied in *Pearson* and related case law.

A. The Carbolite® Brand Name is Not "Inherently Misleading"

1. Commercial speech may only be banned as "inherently misleading" when the government can demonstrate that no disclaimers could cure the alleged deception.

Just prior to FDA's denial of Carbolite®'s petition, in *Whitaker v. Thompson*, No. 01-1539 (D.D.C. Dec. 26, 2002), the court rejected FDA's assertion that the antioxidant vitamin health claim proposed by the plaintiffs in that action was "inherently misleading" and thus unprotected by the First Amendment. The court explained that the Supreme Court has held that "so long as information can be presented in a way that is not deceptive, such information is only potentially misleading -- not inherently misleading." *Whitaker*, Slip op. at 19, *citing In re R.M.J.*, 455 U.S. 191, 203 (1982) (emphasis in original); *see also Revo v. Disciplinary Board of the Supreme Court for the State of New Mexico*, 106 F.3d 929, 933 (10th Cir. 1997), *cert. denied* 521 U.S. 1121 (1997) (for "a particular mode of communication to be inherently misleading, it must be incapable of being presented in a way that is not deceptive." (*citing In Re R.M.J., supra*)). Thus, a claim cannot be banned as "inherently misleading" unless there is no possible way to qualify the claim to eliminate deception. FDA failed to consider further qualifications of the Carbolite® brand name despite the reinforcement of the legal standard provided by this

recent decision. *See also Pearson v. Shalala*, 164 F.3d 650, 657-8, *reh'g denied* 172 F.3d 72 (D.C. Cir. 1999) ("*Pearson I*"), *citing 44 Liquormart, Inc. v. Rhode Island*, rejecting the notion that it was "up to the [government] to choose suppression over a less speech-restrictive policy." 517 U.S. 484, 531-32 (1996) (O'Connor, J., concurring in the judgment), (citation and internal quotation marks omitted). The persistent failure of the agency to respect the narrow confines of its authority to declare speech "inherently misleading" is a matter of serious constitutional concern, and raises the question of whether First Amendment rights can have any meaning for companies if they cannot feasibly be exercised before FDA.

The Supreme Court has recognized the danger in leaving to the government regulator the threshold determination of whether speech is entitled to First Amendment protection and deferring to the regulator's judgment as to whether particular speech is inherently misleading. "Whether the inherent character of a statement places it beyond the protection of the First Amendment is a question of law over which Members of this Court should exercise de novo review." *Peel v. Attorney Registration and Disciplinary Commission of Ill.*, 496 U.S. 91, 108 (1990). If the government "could place speech outside of First Amendment protection by simply declaring the speech 'inherently misleading,' the First Amendment to the United States [Constitution] would be subject to *de facto* modification" by the government. *Bioganic Safety Brands, Inc. v. Ament*, 174 F.Supp.2d 1168, 1180 (D. Colo. 2001).

FDA's classifications of speech as "inherently misleading" are particularly suspect given the string of losses the agency has suffered in federal courts on this issue. *See, e.g., Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51, 67 (D.D.C. 1998) ("In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects, and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the

universe."), *vacated in part by* 202 F.3d 331 (D.C.Cir. 2000); *Pearson I*, 164 F.3d at 655 (rejecting FDA's argument that health claims lacking "significant scientific agreement" are inherently misleading as "frivolous").

As a check on the government's ability to invoke the "inherently misleading" classification of commercial speech, the First Amendment requires the government to shoulder a very heavy burden of proving that the speech can legitimately be suppressed. "It is well established that '[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'" *Edenfield v. Fane*, 507 U.S. 761, 770 (1993), quoting *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71, n. 20 (1983). The government's "burden is not slight; the 'free flow of commercial information is valuable enough to justify imposing on would-be regulators the costs of distinguishing the truthful from the false, the helpful from the misleading, and the harmless from the harmful.'" *Ibanez v. Florida Department of Business and Professional Regulation, Board of Accountancy*, 512 U.S. 136, 143 (1994), quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 646 (1985).

In denying Carbolite®'s brand name petition, FDA has failed to satisfy its burden of demonstrating that the claim can be suppressed because the agency made no attempt to uphold its obligation under the First Amendment to remedy any risk of deception with "more speech" rather than banning commercial speech whenever possible. *Pearson I*, 164 F.3d at 657. Since this basic First Amendment doctrine has been applied specifically in the context of health-related food labeling claims in *Pearson I*, the failure of FDA to take its obligation seriously, and to seek to resolve any genuine issue of deception with Carbolite® by encouraging modified or alternative qualifying labeling, is plainly unjustified.

a) FDA failed to properly evaluate the Carbolite® brand name in the context of the proposed disclaimers.

In *Pearson I*, the court rejected the FDA argument that it could ban certain health claims categorically as "inherently misleading" without first establishing that any genuine risk of deception could not, in fact, be remedied through qualifying information or claims. 164 F.3d at 657. The Court's ruling emphasized the clear preference for "more speech" rather than speech suppression in the well settled body of First Amendment case law. *Id., citing Peel,* 496 U.S. at 110; *In re R.M.J.,* 455 U.S. at 206 n. 20; and *Shapero v. Kentucky Bar Ass'n.*, 486 U.S. 466, 478 (1988).

In *Pearson I*, the court rejected FDA's argument that consumers would not be able to comprehend the proposed health claims in conjunction with the disclaimers suggested because they would be confused if required to interpret a mix of information presented in food labeling themselves. 164 F.3d at 658. Yet in evaluating Carbolite®'s petition, FDA makes the same assertions rejected by that court. It seems that FDA's approach stems from its stubborn refusal to consider the term "Carbolite®" in the context of the entire labeling, and the opportunity to address any genuine concerns through further qualifications. For example, FDA asserts that the total carbohydrate declaration in the Nutrition Facts panel "only highlights that a product bearing 'Carbolite' on its label would not conform to the low carbohydrate claim implied by the brand name," and would therefore confuse consumers. Decision at 7. This faulty logic reveals that FDA is not allowing the Nutrition Facts panel to help define the term "Carbolite®," in violation of the *Pearson I* court's mandate to consider all qualifying language in evaluating whether a claim is misleading. Notably, FDA's existing policy for nutrient content claims relies on the Nutrition Facts box to qualify claims. *See* 21 CFR 101.13(h)(1) (referral statement).

b) FDA failed to consider other potential disclosures that might cure any alleged deception posed by the Carbolite® brand name.

Even if FDA did not consider the proposed language adequate to render the Carbolite® brand name truthful and not misleading, the agency failed to prove that no other language could possibly cure any potential deception -- a showing required before suppressing commercial speech completely. This burden was reiterated clearly in *Pearson v. Shalala,* 130 F.Supp.2d 105 (D.D.C. 2001) (*"Pearson II"*), in which the *Pearson I* plaintiffs filed a second suit after FDA continued to refused to authorize plaintiffs' folic acid health claim, even with clarifying disclaimers. Rejecting FDA's contention that the claim was "inherently misleading" and could not be made non-misleading with a disclaimer or other qualifying language, the district court expressed its frustration at FDA's refusal to abide by the dictates of *Pearson I*, stating that "it is clear that the FDA simply failed to comply with the constitutional guidelines outlined in *Pearson*. Indeed, the agency appears to have at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion." *Pearson II*, 130 F.Supp.2d at 112. The court then reiterated the heavy burden FDA bears in banning speech as "inherently misleading":

> The *Pearson* Court clearly ruled that the FDA may not prohibit a [] claim unless it first makes a "showing" that the claim's alleged "misleadingness" could not be cured through the use of a disclaimer or other types of disclosure. 164 F.3d at 658. The FDA has not made such a showing, and its decision to classify the [claim] as inherently misleading is therefore erroneous. . . . In sum, the FDA has simply failed to adequately consider the teachings of *Pearson*: that the agency must shoulder a very heavy burden if it seeks to totally ban a particular [] claim.

Pearson II, 130 F.Supp.2d at 118.

That burden to requires FDA not only to consider disclaimers presented to the agency, but also to determine independently whether any other potential disclaimers could cure the alleged deception. *Id.* (finding FDA failed to "demonstrate with empirical evidence that disclaimers similar to the ones suggested by the Court of Appeals would bewilder consumers and

fail to correct for deceptiveness. Indeed, the FDA did not consider *any* other disclaimers.") (emphasis in original) (citation and internal quotation marks omitted).

The foregoing authority demonstrates that FDA cannot ban the Carbolite® brand name until it provides empirical evidence that there exists no qualifying language that would cure the alleged deception posed by the name. "The First Amendment does not allow the FDA to simply assert that Plaintiff's Claim is misleading in order to supplant [its] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Whitaker,* Slip op. at 18-19, *citing Ibanez*, 512 U.S. 136, 146 (internal citations omitted). FDA's reference to comments submitted by a single consumer who was allegedly confused by Carbolite®'s labeling does not suffice to satisfy the agency's burden in this regard. The "mere fact that someone is misled by a particular communication is not proof that the communication is inherently misleading." *Bioganic Safety Brands, Inc. v. Ament*, 174 F.Supp.2d 1168, 1181 (D. Colo. 2001), *citing Revo v. Disciplinary Board of the Supreme Court for the State of New Mexico*, 106 F.3d 929, 933 (10th Cir. 1997), *cert. denied* 521 U.S. 1121 (1997). The comments of the diabetes educator who asserted that "counting only a few carbohydrates instead of total carbohydrates on food labels misleads and confuses persons with diabetes" are similarly unavailing to the agency's position. All of the nutrition information of interest to diabetics is present in the Carbolite® labeling. And to the extent that that a diabetic would assume that "Carbolite®" means reduced in total carbohydrates, he would not be harmed because Carbolite® products are in fact reduced in the class of carbohydrates affecting blood sugar levels as compared to the reference food. Any determination the agency may make in reliance on a few public comments cannot be established as representative and is speculative at best.

FDA may not suppress speech merely because it finds that some consumers might have trouble understanding it. Rather, "speech is only 'inherently misleading' if it would be misleading in all circumstances. . . . If there are circumstances in which the speech is not misleading, it is entitled to the protection of the First Amendment." *Id.* at 1181, *citing Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 44 F.3d 726, 731-32 (9th Cir. 1994).

FDA must concede that there are circumstances in which it is not misleading for food labeling to address the nexus between reduced sugar content and carbohydrate count and to present distinctions among types of carbohydrates, because the agency has permitted these types of label statements for decades, as discussed below.

2. Carbolite®'s brand name is not "inherently misleading" because it does not inevitably imply that the product is reduced in total carbohydrates.

FDA made the groundless determination that the brand name Carbolite® is inherently misleading because it suggests to the consumer that the product is reduced or low in total carbohydrates -- not low in sugars -- despite the qualifying information provided in the labeling. This determination is unsupportable in the face of the well established connections made between sugars and carbohydrates in FDA regulations and similar regulations of other government bodies well known to the agency.

a) FDA regulations recognize that "carbohydrate" can meaningfully be qualified to refer to sugars.

As early as 1941, in the preamble to its rules for label statements concerning dietary properties of food for special dietary uses, FDA made clear that consumers are capable of understanding the metabolic distinctions between certain carbohydrates, and that this information is valuable to them in making decisions to purchase food:

> Some carbohydrate substances are not digested or assimilated by the human organism and supply no food energy. Only the

> carbohydrates which may be digested and assimilated are available to the metabolic processes of the organism.
>
> Carbohydrates which are non-available to the metabolic processes have a theoretical caloric value but supply no calories to the human organism.
>
> Information necessary for the purchaser to evaluate a food for use in the control of body weight, or in dietary management with respect to disease, includes a statement on the label of the percent by weight of protein, fat, and available carbohydrates in such food and a statement on the label of the number of available calories supplied by a specified quantity of food.

6 Fed. Reg. 5921, 5924 (Nov. 22, 1941) (emphasis added). While these regulations were repealed in the 1970s, the principles they espouse remain valid, and continue to have meaning for followers of the popular low-carbohydrate diets who may choose food products based upon the content of "available carbohydrates," which Carbolite® describes as "net effective carbs."

Given the FDA's historical recognition of the value to consumers of information concerning available carbohydrates, it is difficult to understand the agency's failure to recognize the importance of the qualifying information accompanying the Carbolite® brand name, or to consider further qualifications consistent with FDA's historical precedents.

The absurdity of FDA's position on the limits of consumer sophistication is made most apparent with respect to the issue of sugar alcohols. FDA states in its Decision that the "agency does not believe, however, that a reasonable consumer understands the difference between sugars and sugar alcohols." Decision at 7. This statement is remarkable because the current FDA regulation of health claims concerning the relationship between dietary sugar alcohols and dental caries expressly permits label statements discussing the distinctions between sugar alcohols and sugars and other "fermentable carbohydrates" (*i.e.*, "net effective carbs"). *See* 21 C.F.R. 101.80. The dental caries health claim regulation exposes that the agency itself has recognized that consumers are capable of understanding qualifying labeling which makes

distinctions between types of carbohydrates, specifically including with respect to "fermentable carbohydrate" and "sugar alcohols" in the overall context of the product labeling. 21 C.F.R. 101.80. Foods that qualify as "sugar free" under Section 101.60(c)(1)(i) may include the following qualifying statements:

- "Sugar alcohols do not promote dental caries. Sugar alcohols are more slowly metabolized by bacteria to form some acid. The rate and amount of acid production is significantly less than that from sucrose and other fermentable carbohydrates." (101.80(b))
- Statements regarding the "[r]elationship between dietary carbohydrates [referring to "fermentable carbohydrates] and dental caries" (101.80(a)(1))
- Statements regarding the relationship between "[f]requent consumption of fermentable carbohydrates, such as dietary sugars and starches," and tooth decay. 101.80(a)(2)
- The statement that "[f]requent consumption of fermentable carbohydrates, such as dietary sugars and starches," constitutes a risk factor for dental caries (101.80(d))
- The statement that "Dietary sugar alcohols are significantly less cariogenic than dietary sugars and other fermentable carbohydrates." (101.80(a)(4)).

These authorized label statements put forth to consumers precisely the same type of information that Carbolite®'s labeling is intended to convey. That is, they allow the labels of qualified foods to address the distinctions between carbohydrates from sugars or "fermentable carbohydrates" (or "net effective carbs") and sugar alcohols, which are carbohydrates having different functional effects on the body. Clearly, FDA would not have authorized these label statements for qualified foods under 101.80 if the agency had evidence that these statements were inherently misleading and confusing to consumers. Yet FDA has banned the use of the Carbolite® brand name precisely because the agency assumes that consumers cannot understand the distinction between total carbohydrates and sugar carbohydrates and will necessarily assume any reference to carbohydrates refers to "total carbohydrates."

The dental caries health claim regulation serves to demonstrate that FDA cannot meet its burden under the First Amendment of proving that Carbolite®'s claim is incapable of

being qualified in a manner that renders it truthful and nonmisleading. To the contrary, the label statements authorized by the dental caries health claim serve as models for the types of disclosures that might be constructed with the Carbolite® brand name and that should have been obvious to FDA in satisfying its First Amendment obligations.

b) Former Canadian food labeling regulations allowed "carbohydrate-reduced" claims comparable to the Carbolite® labeling.

The failure of FDA to consider its own regulatory precedents is even more remarkable considering the comparable connections made between sugar and carbohydrate well established under international regulatory schemes that are familiar to the agency. From 1974 until January 1 of this year, Canadian food labeling regulations allowed a claim of "carbohydrate-reduced" for foods for special dietary use.[1] Those regulations defined a carbohydrate-reduced food as a food

> (a) that would, if it were not carbohydrate-reduced, derive at least 25 per cent of the calories contained in that food from its carbohydrate content; and
>
> (b) that, when ready to serve,
>
> (i) contains not more than 50 per cent of available carbohydrate normally found in that food when it is not carbohydrate-reduced as determined by an acceptable method, and
>
> (ii) provides no more calories than would be provided if it were not carbohydrate-reduced.

B.24.004 (emphasis added). According to this definition, a "carbohydrate-reduced" food is one in which available -- not total -- carbohydrates have been reduced. "Available carbohydrates" has the same meaning as "net effective carbs" and "fermentable carbohydrates." The total

[1] These regulations for claims for carbohydrate-reduced diets were repealed because Health Canada determined the claims no longer provided useful dietary guidance for diabetics. In the March 18, 1998 letter to All Interested Parties regarding proposed revisions to the criteria for nutrient content claims (Appendix 1, at 20), Health Canada explains that "[t]he claim 'carbohydrate-reduced' was used in the past to identify foods recommended for carbohydrate-reduced diets which were used for the dietary management of diabetes. However, carbohydrate restriction per se is no longer part of the dietary guidance in the management of diabetes."

carbohydrate count is irrelevant for the purpose of this claim, because the valuable information to the consumer is the data concerning available carbohydrates.

The Canadian regulations set forth additional labeling requirements for foods bearing the "carbohydrate-reduced" claim:

> (1) The label and advertisement of a carbohydrate-reduced food shall carry the statement that the food is recommended for "carbohydrate-reduced diets"
>
> (2) The label of a carbohydrate-reduced food shall carry
>
> (a) the expression "carbohydrate-reduced" on the principal display panel in close proximity to, and in the same size type as, the common name; and
>
> (b) the following information, shown grouped together and given equal prominence on the label, per serving of stated size, namely,
>
> (i) its energy value, expressed in calories, and
>
> (ii) its protein, fat and carbohydrate content, expressed in grams.

B.24.009. Notably, this is precisely the information that Carbolite® proposed to accompany its brand name. It is plain that Health Canada believed that consumers would not be misled by a "carbohydrate-reduced" claim even on a food for which total carbohydrates were not reduced, where nutrition information such as that contained in Carbolite®'s labeling is also provided. Accordingly, it is difficult to conceive why FDA would assume that American consumers would be irredeemably confused by a statement readily understood by our neighbors to the North.

Further, the Canadian regulations demonstrate that Health Canada recognized that its citizens could understand the relationship between claims about sugars and carbohydrates. Under those regulations, a sugar-free food was defined in part as a carbohydrate-reduced food. B.24.005. The label and advertisement of a sugar-free food was required to carry the statement that the food is recommended for "carbohydrate-reduced diets" (referring to a reduction in available carbohydrates). B.24.010. This is the mirror image of Carbolite®'s proposed labeling,

in which the claim "zero sugar" would accompany the brand name "Carbolite®" on qualifying foods. These Canadian regulations demonstrate that it is not inherently misleading to link "sugars" and "carbohydrates," and that doing so can provide truthful, meaningful and useful dietary information to consumers.

B. Model Qualifying Language Would Render the Carbolite® Brand Name Truthful and Not Misleading.

FDA's central rationale for banning the Carbolite® brand name is the false assumption that the name implies a reduction in total carbohydrates. There is a simple cure for this concern -- add a disclaimer that the product is "not reduced in total carbohydrates." While Carbolite® believes that such verbiage would be redundant in light of the declaration of the total carbohydrate content in the Nutrition Facts and Carbohydrate Facts boxes, it is incomprehensible that FDA failed even to consider this approach to upholding its First Amendment obligations.

In order to discharge its burden under the First Amendment for regulation of commercial speech, FDA should look to its dental caries health claim regulation and the former Canadian regulations of "carbohydrate-reduced" claims for model qualifying language that would render the Carbolite® brand name truthful and not misleading. In fact, the model language suggested by FDA's own existing food labeling policies should have been obvious to the agency, and should have been considered in FDA's initial evaluation of Carbolite®'s petition. *See Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993) (stating that the government must consider "obvious less-burdensome alternatives to the restriction on commercial speech"). Although it is the government's duty to explore any potential disclaimers before banning speech, Carbolite® submits the following qualifying language for FDA's consideration, which draws upon the obvious U.S. and Canadian regulatory precedents:

> Carbolite® products are specially formulated with sugar alcohol sweeteners and are designed for sugar controlled diets, including

> weight-loss diets[2] restricting carbohydrates having a notable effect on blood sugar ("net effective carbs"). Carbolite® products are not necessarily 'light' or 'low' in total carbohydrates, calories or fat. See Nutrition Facts for information on carbohydrate, fat, and calories.

In addition, the following statement declaring the fermentable carbohydrate content of each food product would appear on the principal display panel ("PDP") adjacent to the Carbolite® brand name: "x grams fermentable carbohydrate from sugars and starches (see back panel for nutrition information)." The PDP would also bear the claims "zero sugar" and "reduced sugar,"[3] with the required disclaimer that the food is "low calorie," reduced calorie," or "not a low calorie" food, as appropriate. Moreover, the Carbohydrate Facts box would appear on every product bearing the Carbolite® brand name, along with the mandatory Nutrition Facts box.[4] The Carbohydrate Facts box would provide the following description of "net effective carbs": "Includes only those carbs that cause a noted effect on blood sugar ('fermentable carbs')." This information, taken together, would accurately characterize the level and metabolic effect of sugar and other carbohydrates in the product.

Because qualifying language can accurately convey that the product is low in sugar carbohydrates, FDA's argument that the brand name is not only misleading but also

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[2] FDA's assertion that Carbolite®'s model claim "implies, on its face, that restricting carbohydrates leads to weight loss" is baseless and unsupported by any empirical evidence that consumers would be misled by the statement. Decision at 8.

[3] Carbolite® does not agree with FDA that 21 C.F.R. § 101.60(c) precludes the use of the implied synonyms "zero sugar carbs" and "0 sugar carbs" for sugar content claims, since that provision refers to use of terms "such as" those enumerated, and does not exclude other equivalent terms. Moreover, under the *Pearson* mandate that FDA seek to qualify claims before banning them, FDA should have considered restricting these label statements rather than refusing to approve Carbolite®'s petition. Again, however, in the interest of compromise, Carbolite® is willing to forego use of these terms on its labeling, and notes that the proposed labeling submitted with its initial petition did not contain these implied synonyms.

[4] The nutrition information appearing on all products qualified to bear the Carbolite® brand name clearly substantiates the proposed label claims. See Nutrition Information Chart attached as Appendix 2.

untruthful must fail, as that argument was based upon the assumption that the brand name necessarily implied a reduction in total carbohydrates. Decision at 5.

Further, the term "Carbolite®" is not misleading by virtue of the suffix "lite" because the proposed disclaimers expressly state that the product is not low in calories or fat. FDA's contention that "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" (Decision at 5) is groundless. The Supreme Court rejected a similar argument in *Ibanez v. Florida Department of Business and Professional Regulation, Board of Accountancy*, 512 U.S. 136 (1994). In that case, the Board of Accountancy reprimanded an attorney for advertising her credentials as a Certified Financial Planner because the designation -- particularly the word "certified" -- was regulated under the definition of the similar term, "Certified Public Accountant." The Board argued this resemblance rendered the use of the Certified Financial Planner designation "inherently misleading" because the word "Certified" would necessarily imply state licensure, but failed to propound any evidence of deception. Consequently, the Supreme Court held that the Board's action was incompatible with First Amendment restraints on official action. "Given the complete absence of any evidence of deception, the Board's concern about the possibility of deception in hypothetical cases is not sufficient to rebut the constitutional presumption favoring disclosure over concealment." 512 U.S. at 145 (citation and internal quotation marks omitted). Similarly, FDA cannot ban the use of the term "Carbolite®" without empirical evidence that consumers will believe the suffix "lite" necessarily implies the FDA-authorized claim for low in calories or fat.

FDA's argument regarding consumers' perception of the suffix "lite" is reminiscent of the argument rejected so forcefully by the court in *Pearson I.* That court understood government's argument to mean that

> health claims lacking in "significant scientific agreement' are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale.* It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. . . . We reject it."

Pearson I, 164 F.3d at 655, citing *Peel*, 496 U.S. at 105 (rejecting paternalistic assumption that the recipients of a letterhead are "no more discriminating than the audience for children's television."). Here FDA similarly argues that consumers will be "hypnotized" by the suffix "lite" and will be incapable of discerning the meaning of the explicit disclaimer that Carbolite® products are not low in calories or fat. Such a denigrating view of the reasonable consumer cannot stand as a basis for suppressing speech.

The foregoing proposed qualifications can therefore adequately render the Carbolite® brand name truthful and not misleading. If FDA does not agree, then the agency bears the burden of demonstrating that no other possible disclaimers could cure the alleged deception before it can ban the brand name completely.

II. FDA's Denial of Carbolite®'s Petition Was Made in Violation of the Administrative Procedure Act

The Administrative Procedure Act ("APA") prohibits government agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). A reviewing court would determine whether the agency has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action. . . ." *Motor Vehicle Manufacturer's Ass'n v. State Farm Mutual Ins. Co.*, 463 U.S. 29, 43 (1983). FDA has plainly failed to satisfy this standard in denying Carbolite®'s brand name petition, for three reasons.

First, the agency failed to consider the relevant regulatory provisions indicating the long history of label claims linking sugars to carbohydrates, and therefore did not examine the data relevant to its determination. An agency rule would be considered arbitrary and

capricious if the agency "offered an explanation for its decision that runs counter to the evidence before the agency." *Id.* Here, FDA explained its denial of Carbolite®'s petition on the faulty grounds that consumers could not be made to understand the relationship between sugar carbohydrates and others, and their varying effects on the body. Its explanation that the "agency does not believe, however, that a reasonable consumer understands the difference between sugars and sugar alcohols" (Decision at 7) clearly runs counter to the evidence before the agency that led it to permit label statements regarding the distinctions between sugars and sugar alcohols in the dental caries health claim regulation. 21 C.F.R. § 101.80. Moreover, it is arbitrary and capricious for the agency to authorize the label statements in § 101.80 while denying the Carbolite® brand name petition that proposes labeling to the same effect.

Second, FDA failed to consider any disclaimers other than those proposed by Carbolite®, in violation of its First Amendment obligations. That same failure by FDA in *Pearson II* led the court to conclude that the agency's determination that the claim was inherently misleading was "arbitrary and capricious." 130 F.Supp.2d at 118-119. Moreover, "an agency's decision may be overturned under the APA when it 'has failed to respond to specific challenges that are sufficiently central to its decision.'" *Whitaker*, Slip Op. at 23, citing *International Fabricare Institute v. E.P.A.*, 972 F.2d 384, 389 (D.C. Cir. 1992). Here, FDA failed to respond to the challenge mandated by the First Amendment that the agency consider all possible qualifying language before banning a claim.

Finally, the APA requires FDA to explain why it rejects proposed label claims. *Pearson I*, 164 F.3d at 660. FDA not only failed to consider any qualifying language other than that proposed by Carbolite®, but also failed to articulate its reasons for refusing to do so. Accordingly, FDA's arbitrary and capricious denial of Carbolite®'s petition stands in violation of the APA, and must be reversed upon reconsideration.

III. FDA's Denial of Carbolite®'s Petition Renders Meaningless the Provisions Authorizing Petitions for Implied Nutrient Content Claims in a Brand Name

In its Summary and Conclusion to its Decision, FDA suggests 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" Decision at 14. The agency states that if such 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. *Id.* These assertions essentially render meaningless 21 C.F.R. § 101.69(o) and section 403(r)(4)(A)(iii) of the Act.

As an initial matter, this petition demonstrates that FDA has no legal authority to conclude that "Carbolite®" unavoidably means "low carbohydrate" and that it is impossible to communicate the meaning of the term to refer to sugars and starches (*i.e.*, "fermentable carbohydrates") rather than total carbohydrate. Accordingly, FDA has no basis to conclude that a petition under 101.69(m) for a new "low carbohydrate" nutrient content claim would be a prerequisite for the authorization of Carbolite®'s petition for an implied nutrient content claim in a brand name. Because the Carbolite® brand name is consistent with the authorized express nutrient content claims for "zero sugar" and "reduced sugar," it is the proper subject of a petition under 101.69(o) and section 403(r)(4)(A)(iii) of the Act.

As noted in Carbolite®'s initial petition, petitions for implied claims in a brand name are excluded from the requirement -- applicable to petitions for expressed or implied nutrient content claims -- that the characterization of the level made in the claim use terms which are defined in FDA regulations. *See* 403(r)(2)(A) of the Act; 21 C.F.R. 101.65(a)(1)-(2). Rather, FDA must grant a petition for an implied claim in a brand name if the agency finds that such

claim is not misleading and is consistent with terms defined by FDA under section 403(r)(2)(A)(1) of the Act. This distinct treatment of petitions for implied claims in a brand name cannot be discounted without eroding the value and purpose of the authorizing provisions. *See* Petition at 6-8.

FDA's reading of the relevant statutory and regulatory provisions ignores basic principles of statutory construction and is not entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). *Chevron* mandates a two-part inquiry for judicial review of an agency's construction of a statute it administers. First, a court considers whether Congress spoke directly to the question at issue. If so, "that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. If the statute is unclear, however, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. FDA's interpretation of the requirements for an implied claim in a brand name is simply not reasonable, and therefore are not entitled to *Chevron* deference, because it renders the distinguishing features of section 403(r)(4)(A)(iii) of the Act meaningless.

In striking down another attempt by FDA to mischaracterize the language of its enabling statute, the Second Circuit recently reiterated that courts must "give effect, if possible, to every clause and word of a statute." *National Health Alliance v. FDA*, ___ F. 3d ___, 2003 WL 139789 (2d Cir. Jan. 21, 2003) at *9 (referencing *Williams v. Taylor*, 529 U.S. 362, 404 (2000) (describing this rule as a "cardinal principle of statutory construction") (other citations omitted). FDA's failure to do so rendered its interpretation not entitled to deference under *Chevron* in that case. *Id.*

Similarly, FDA's interpretation of the provisions authorizing implied claims in a brand name makes no sense under general principles of statutory construction. If Carbolite®

would need to have authorized "low carbohydrate" and "lite carbohydrate" express approved claims with criteria set out in regulations established through rulemaking initiated through a burdensome § 101.69(m) petition, it is unclear why the company would need a petition under 403(r)(4)(A)(iii) and § 101.69(o) at all and what benefit a petition under those provisions would provide, since the brand name would be essentially identical to the authorized express claim. Moreover, FDA's suggested approach would essentially burden a single company with the job of getting a broad claim approved for use by the whole industry before it can use its own brand name. The distinct statutory and regulatory provisions for a petition for an implied claim in a brand name clearly counsel against such an approach.

These same principles of statutory construction invalidate FDA's argument, expressed only in a footnote, that the term Carbolite® is not consistent with the terms defined by FDA pursuant to section 403(r)(2)(A)(i) of the FD&C ACT. See Decision at 4, fn. 4. As explained in Carbolite®'s initial petition, the statutory phrase "consistent with" is clearly distinguished from the policy that has been developed for nutrient content claims of general application, which must use a term defined by regulation to characterize the nutrient level. See Petition at 4. Again, this distinction must be given effect according to its plain meaning. "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* Roget's II The New Thesaurus at 205 (1988).

FDA's determination that the Carbolite® brand name is not "consistent" with nutrient content claims for "zero sugar" and "reduced sugar" derives from the agency's failure to consider its own regulations which demonstrate that a "coherence," "congruity" and

"correspondence" between carbohydrate content and sugar claims can be established and understood by consumers. The evidence from the regulatory record plainly demonstrates that the term "Carbolite®" is "consistent with" such defined sugar claims.

Further, FDA's attempt to require near-identity between an implied claim in a brand name and an authorized express claim is in direct contravention to the agency's broad approach to implied claims. The provisions at 21 C.F.R. § 101.13(i) and 101.65(c) take a broad approach to the definition of implied claims in a manner that permits FDA to encompass within its regulations a broad range of claims. For example, "oat bran" can mean "fiber," and in such a case the product bearing the "oat bran" statement would be subject to the requirements for implied nutrient content claims. See 21 C.F.R. § 101.65(c). It is unjustifiable for FDA to take this broad approach to implied claims when doing so gives the agency great leverage to burden commercial speech, and at the same time to take a narrow reading of the implied claims approval process under § 101.69.(o). Such a baseless distinction between regulatory approaches is arbitrary and capricious in violation of the APA. Moreover, this unfounded disparity in the agency's manner of restricting constitutionally protected commercial speech cannot survive First Amendment scrutiny.

IV. Prohibiting the Use of the Carbolite® Brand Name Constitutes a Taking, Without Just Compensation, Under the Fifth Amendment

FDA erroneously states that "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." Decision at 11. This statement betrays FDA's failure to acknowledge that the First Amendment principles bear directly on the relevant Fifth Amendment takings analysis, and prohibit a government agency from stating, essentially, "you can't speak unless we say you can." In fact, the constitutional framework is precisely the reverse -- a party's freedom to speak may not be abridged unless the

government satisfies its burden of proving, based on evidence, that the restriction is necessary to remedy a concrete harm presented by the speech. It is astonishing that FDA would even make the quoted assertion, when this same contention was strongly dismissed in *Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51, 67 (D.D.C. 1998), *vacated in part by* 202 F.3d 331 (D.C.Cir. 2000), where the court held that in asserting that claims "are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe."

Carbolite® is fairly entitled to rely upon the protection of the First Amendment in shaping its investment-backed expectations. FDA cannot be heard to argue that Carbolite® unreasonably invested in its brand name because "Carbolite® knew (or should have known) that the trademark would also be subject to FDA regulations governing nutrient content claims," Decision at 12, and was "on notice that the propriety of its brand name and trademark might be challenged by FDA," Decision at 14. Carbolite® need not waive its First Amendment rights when deciding to do business in a government-regulated field. Rather, the company may legitimately assume that any government regulation of its label statements will be performed in conformance with the First Amendment and within the scope of the agency's statutory authority. Carbolite® need not frame its expectations by hypothesizing the impact of *ultra vires* FDA action.

Further, Carbolite® was entitled to shape its expectations based upon an appropriate reading of the governing statute that gives effect to each individual provision. Similarly, the fundamental statutory construction principles discussed above render baseless FDA's contention that its denial of Carbolite®'s petition does not constitute a taking because the company can pursue other, highly burdensome, regulatory options to get its brand name blessed by FDA. *See* Decision at 12.

Finally, FDA cannot rely on its old standby argument that "FDA's decision to deny the petition serves to protect and promote the public health" and therefore does not constitute a taking. Decision at 13. The agency asserts that "it is well established that court 'afford particular deference to governmental action taken in order to protect the public interest in health, safety, and welfare,'" Decision at 12 (citations omitted), despite the fact that Federal courts have repeatedly thwarted FDA's attempts to restrict speech ostensibly for public health reasons. As discussed in detail above, FDA's denial of Carbolite®'s petition is not entitled to deference because it was conducted in violation of fundamental First Amendment dictates. As the *Pearson I* court observed, "[a]lthough the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech." 164 F.3d at 658. Because FDA has failed to satisfy its burden of justifying the speech restriction by proving it is necessary to prevent concrete harm, its ban of the Carbolite® brand name constitutes a taking without just compensation in violation of the Fifth Amendment.

V. Enforcement Action Against Carbolite®'s Use of its Brand Name Must Be Stayed

FDA's denial of Carbolite®'s petition exceeded the agency's authority as bounded by overarching First Amendment dictates. The agency therefore lacks authority to take any enforcement action against the use of the Carbolite® brand name under that decision or under the June 2001 warning letter. Any such enforcement action must be stayed pending reconsideration of the petition and the issuance of a decision grounded in governing First Amendment principles and basic rules of statutory construction, and within the scope of valid agency action under the APA.

The harm that would accrue to Carbolite® if the effect of the Decision is not stayed greatly outweighs any potential countervailing considerations. "The loss of First

Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Pearson II*, 130 F.Supp.2d at 119, quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (citations omitted). And as the Supreme Court has noted, "opportunities for speech," if suppressed, "are irretrievably lost." *City of Lakewood v. Plain Dealer Publ'g Co.*, 486 U.S. 750, 758 (1988). The court in *Whitaker* recognized this grave harm when it granted plaintiffs' motion for a preliminary injunction enjoining FDA from taking any action which would prevent the use of the proposed health claim as proffered or with reasonable disclaimers. Although the court acknowledged the role FDA plays in protecting vulnerable consumers from fraud in the labeling and marketing of foods and dietary supplements, the court concluded that even if plaintiffs' claim was "potentially" misleading, "the resulting injury that could flow to consumers cannot compare, as a matter of law, with the First Amendment injury" plaintiffs suffered at the loss of their First Amendment freedoms. *Whitaker v. Thompson*, Slip op. at 34.

Accordingly, a refusal to stay FDA enforcement action against the use of the Carbolite® brand name pending reconsideration cannot be justified, particularly given the financial harm the company will suffer due to even a temporary loss of use of the Carbolite® brand name. As noted in Carbolite®'s initial petition, the commercial importance and informational value of brand names in the effective marketing of food products cannot be overstated. Carbolite® has established substantial name recognition and good will in the marketplace associated with the Carbolite® brand name, and the name is one of the company's most valuable and important business assets. The loss of the Carbolite® brand name, even just for the period of time it would take for FDA to reconsider Carbolite®'s petition, would result in a loss of brand recognition that could not readily be recovered, and would inevitably cause sales of Carbolite® products to plummet.

Additionally, it makes little sense to require Carbolite® to incur the substantial costs of relabeling its products when on reconsideration FDA should grant Carbolite®'s brand name petition for the reasons discussed above. Further, even the temporary suspension of the use of the Carbolite® brand name would lead to confusion among consumers dedicated to purchasing Carbolite® products for inclusion in low carbohydrate and sugar-controlled diets.

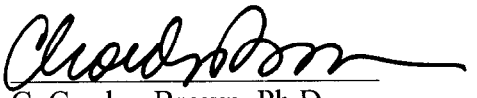
In sum, FDA must stay the effect of its Decision, and any enforcement action under the June 2001 warning letter with respect to the use of the Carbolite® brand name, because the agency has no authority to proceed with any such enforcement action, and cannot justify the harm Carbolite® would incur if such action is taken pending reconsideration of the Decision.

VI. Conclusion

For the foregoing reasons, Carbolite® requests that FDA reconsider its decision to deny the company's petition for an implied nutrient content claim in a brand name, and instead grant the petition and authorize use of the implied claim in the context of the proposed qualifying language or other disclaimer the agency finds appropriate. Carbolite® further requests that FDA stay the effect of its denial of Carbolite®'s petition, as well as any enforcement action with respect to FDA's June 2001 Warning Letter regarding the Carbolite® brand name, pending reconsideration of the petition.

Respectfully submitted,

CARBOLITE® FOODS, INC.

By: 

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