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

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

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Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, Maryland 20852

Re: Reopening of the Comment Period – Food Labeling: Nutrient Content Claims, General Principles
FDA Docket Nos. 1994P-0390 and 1995P-0241

These comments are submitted on behalf of Carbolite Foods, Inc. ("Carbolite"). Carbolite produces alternative food products which have been specially formulated for consumers adopting dietary weight loss regimens that restrict the intake of certain carbohydrates ("low carbohydrate" or "low carb" regimens). The product lines produced by Carbolite include a diverse variety of alternative candies, snack bars, beverage, shake and bakery product mixes. Carbolite was one of the first producers of alternative candies formulated for use in "low carbohydrate" weight loss regimens. The company now offers an extensive line of such alternative food products, which are distributed internationally. As an industry leader, Carbolite understands the critical need of consumers to receive accurate, substantiated and meaningful information in food labeling concerning the carbohydrate components of food that are important in "low carb" dietary regimens, and the need for food companies to use flexible and creative methods of expression to ensure that the carbohydrate information disseminated is meaningful and responsive to genuine consumer needs.[1]

[1] See Carbolite's discussion of the need for accurate and meaningful information in food labeling that distinguishes the carbohydrate components of food that are typically restricted in "low carbohydrate" regimens from other carbohydrates for which consumption is encouraged (e.g., dietary fiber), in Carbolite's Citizen Petition filed today concerning Labeling Claims Using "Net Effective Carbohydrates" and Similar Terms, a copy of which is attached to these Comments as Attachment A.

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Carbolite appreciates FDA's reopening of the comment period on these important issues concerning flexibility in disseminating nutrition information through food labeling. As the agency has recognized in promulgating its Consumer Health Information for Better Nutrition Initiative, food labeling can be a powerful tool for conveying information to consumers regarding the relationship between diet and health. However, the value of this tool is limited by an overly restrictive regulatory construct that hinders creativity in crafting label claims in a manner that will best inform and appeal to the target audience.

Carbolite's comments address only the proposed use of unlisted synonyms for nutrient content claims. For the reasons discussed below, Carbolite urges FDA to adopt a regulatory approach that allows for flexibility and creativity in the construction of truthful and nonmisleading claims that are synonymous and consistent with defined nutrient content claims.

I. Carbolite Supports the "Anchored Synonym" Approach Proposed by NFPA

Carbolite believes that the "anchored synonym" proposal offered by the National Food Processors Association ("NFPA") in its 1994 citizen petition represents a promising approach to implementing the nutrient content claim provisions of section 403(r)(4) of the Federal Food, Drug and Cosmetic Act ("FDCA") in a manner that is consistent with the governing First Amendment standards. The First Amendment establishes the premise that the speaker has the right to convey the message he desires in the language of his choice. The United States Supreme Court highlighted the centrality of this principle in *Riley v. Nat'l Federation of the Blind of North Carolina*, 487 U.S. 781, 790-791 (1988), explaining that the "First Amendment mandates that we presume that speakers, not the government, know best both what they want to say and how to say it." The anchored synonym approach would give food manufacturers greater flexibility to use their marketing expertise to promote a nutrient content claim in a way that conveys the message in a creative, effective, and nonmisleading manner, and without suffering the undue delay and procedural hurdles that accompany the current premarket clearance system.

A. FDA's Proposed Restrictions Are Not Necessary to Prevent Deception

While Carbolite appreciates the significant step FDA took to authorize anchored synonyms in the agency's 1995 proposal, we believe that greater reforms are needed to satisfy First Amendment standards. In particular, prescriptive approaches, such as the proposal to require the listed term to appear immediately adjacent to and at least half as prominent as the most prominent use of the unlisted synonym are unduly burdensome on free speech and are unlikely to survive First Amendment scrutiny.

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 no more extensive than necessary to remedy a concrete harm presented by the specific speech at issue. *See, e.g., Edenfield v. Fane*, 507 U.S. 761, 770-71 (1993) ("a governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree."). FDA has not

articulated with particularity the harm that will follow from allowing anchored synonyms without these restrictions.

1. Existing Statutory Safeguards Can Prevent Deception

Carbolite believes that ample safeguards already exist to prevent deception in the use of unlisted synonyms on labels where the defined nutrient content claims also appear. Section 403(a) of the FDCA states that a food shall be deemed misbranded if its labeling is false or misleading in any particular, and section 201(n) provides that labeling may be deemed misleading if it fails to reveal material facts in light of the representations made. Section 403(f) mandates that required label statements must appear with sufficient conspicuousness, relative to other statements in the labeling, to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. These statutory provisions take a holistic approach to food labeling, and enable FDA to examine a food's labeling in its entirety in order to determine whether the "take away" message is misleading or deceptive.

2. FDA Must Examine Synonyms in the Context of the Entire Product Label

In order to satisfy its burden under the First Amendment, FDA must consider the use of anchored synonyms in the context of the entire product label before concluding that they are deceptive. The court rejected a contrary approach in *Pearson v. Shalala*, 164 F.3d 650, 658, *reh'g denied* 172 F.3d 72 (D.C. Cir. 1999) ("*Pearson I*"), dismissing FDA's argument that consumers would not be able to comprehend the proposed health claims in conjunction with disclaimers because they would be confused if required to interpret a mix of information presented in food labeling themselves.

The Federal Trade Commission ("FTC") expressly recognizes the importance of context in evaluating the use of synonyms in nutrient content claims. In its Enforcement Policy Statement on Food Advertising, the FTC observes that a phrase or synonym may be misleading depending on the context of an advertisement. FTC states that the "Commission will examine advertising to ensure that claims that characterize the level of a nutrient, including those using synonyms that are not provided for in FDA's regulations, are consistent with FDA definitions." Enforcement Policy Statement on Food Advertising, Section III.A.3. (May 1994), available at www.ftc.gov/bcp/policystmt/ad-food.htm.

Notably, this FTC policy recognizes that a "claim" is broader than the unlisted synonym itself, and that the claim *which includes* unlisted synonyms must be consistent with FDA's listed claims. This position supports the broad view of "claim" advocated by NFPA in its 1994 petition, and with which Carbolite agrees.

3. FDA Can Take Enforcement Action Against Misleading Claims

In order to ensure that claims using unlisted synonyms are not misleading, FDA can draw upon the full arsenal of enforcement tools at its disposal, and need not take a prescriptive or prophylactic speech-restrictive approach in order to prevent deception. The Supreme Court has emphasized that the First Amendment favors case-by-case adjudication. In

Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985), the Court struck down regulations on advertising by lawyers, rejecting the government entity's argument that such advertising would be too difficult to police. The Court emphasized that the First Amendment does not permit the government to suppress "truthful and nondeceptive advertising simply to spare itself the trouble of distinguishing such advertising from false or deceptive advertising," for "[t]he 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." *Id.* at 646.

Further, the *Zauderer* Court contrasted the State's regulatory scheme to the enforcement model employed by the FTC, finding the FTC approach to be instructive in demonstrating that deception can be curbed without employing broad prophylactic measures. 471 U.S. at 645, 649. In particular, the Court noted that Commission's success in suppressing deceptive use of visual media, and concluded, "[g]iven the possibility of policing . . . advertisements on a case-by-case basis, the prophylactic approach taken by [the State] cannot stand." 471 U.S. at 649. The FTC enforcement model is particularly instructive here because the Commission's policies expressly address unlisted synonyms. Plainly, FTC believes an enforcement approach is adequate to prevent deception in this context. Moreover, the court in *Pearson I, supra,* suggested that adjudication would seem a more natural fit for the individualized determination regarding scientific support for health claims. 164 F.3d at 652. That same logic would apply equally to FDA's analysis of the deceptive potential of nutrient content claims using unlisted synonyms, and FDA should follow FTC's enforcement approach in this regard. Imposition of the prescriptive restrictions proposed in 1995 will render the anchored synonym approach unattractive to most marketers, and therefore this supposed reform of the nutrient content claim requirements will be of little consequence to the food industry.

II. Anchored Synonyms Can Be Understood By Consumers

A. FDA Bears the Burden of Proving that Anchored Synonyms Would Mislead

FDA has requested data or information establishing whether consumers would be able to understand and not be misled by unlisted synonyms that are tied to defined terms. The agency asserted in its 1995 proposal that it would not be able to finalize the proposed change unless it received evidence demonstrating that consumers would be able to understand the synonyms. This approach misconstrues FDA's burden under the First Amendment with respect to government-imposed speech restrictions.

"It is well established that '[t]he party seeking to uphold a restriction on commercial speech carries the burden of justifying it.'" *Edenfield, supra,* 507 U.S. at 770, quoting *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 71, n. 20 (1983). The Supreme Court has explained that the government's "burden is not slight." *Ibanez v. Florida Department of Business and Professional Regulation, Board of Accountancy*, 512 U.S. 136, 143 (1994).

This burden may not be shifted to the speaker. In *Riley, supra*, the Supreme Court addressed a state statute that declared that a fee for professional charitable solicitors exceeding 35% was presumed unreasonable but permitted the fundraiser to rebut this presumption. In

striking down the statute, the Court explained that it would not allow a measure that required the speaker to prove "reasonableness." 487 U.S. at 793. FDA's request that promoters of unlisted synonyms demonstrate that their claims are not misleading, both in its call for comments and in the petition requirements under 101.69(n), similarly and impermissibly shifts the burden of proof to the would-be speaker. The burden properly rests with FDA to prove, through evidence, that the proposed speech will in fact mislead consumers.

B. FDA Can Determine that Anchored Synonyms Will Not Mislead

In order to determine whether consumers will understand that unlisted terms are synonymous with established nutrient content claims, FDA can readily turn to basic resources such as a current dictionary or thesaurus. If the undefined term appears in the dictionary definition or thesaurus entry for the listed term, then FDA should conclude that consumers will comprehend that the terms are equivalent.

Some current or trendy terminology may not appear in a dictionary or thesaurus, but FDA has experience in dealing with fanciful terms used by the public in implementing the common or usual name regulations, which recognize that terms gain meaning from patterns of use. FDA should also recognize that synonyms can be conceptual as well as literal word equivalents, for synonymous ideas include "logical agreement between things or parts," "coherence," "congruity," and "correspondence." *See* Roget's II The New Thesaurus at 205 (1988).

If FDA is unable to adequately compare the listed and unlisted terms alone, it must conduct an analysis of the use of the undefined synonym in the context of the entire product label, as discussed above. If such analysis is still not sufficient to reveal consumer understanding, then the agency bears the burden of conducting consumer research to demonstrate that the unlisted synonym is misleading and may not be used.

III. FDA's Current Premarket Clearance Approach to Unlisted Synonyms Does Not Comport with the First Amendment

FDA also requests comments on whether the current petition process in § 101.69(n) for synonyms is too burdensome, and if so, why. As a threshold matter, Carbolite observes that such a preapproval scheme generally will be suspect because the First Amendment favors a case-by-case approach that permits analysis of the particular harm to be addressed by the speech restriction in every instance, such as that conducted through adjudication or enforcement. The Supreme Court explained in *United States v. Nat'l Treasury Employees Union*, 513 U.S. 454, 468 (1995), that "the Government's burden is greater with respect to [a] statutory restriction on expression than with respect to an isolated disciplinary action." In regulating speech before it occurs, the government faces a nearly insurmountable hurdle, in all but the most obvious cases of anticipated harm, to demonstrate that concrete harm will necessarily follow the speech unless the government intervenes.

Also problematic is the fact that, as discussed above, this rule unlawfully shifts the burden to the petitioner to demonstrate that the proposed synonymous term would not be misleading to consumers.

Finally, the costs, procedural hurdles and lengthy time frame for evaluation make the petition process sufficiently burdensome to industry that many manufacturers are discouraged from attempting the process. This means that many truthful, useful and nonmisleading synonymous claims may not be expressed because of the "speech chilling" effect of this regulation. Even when FDA grants a petition, the lawful synonym will have been suppressed for at least 105 days under the rule. "The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Pearson v. Shalala*, 130 F. Supp.2d 105, 119 (D.D.C. 2001) ("*Pearson II*"), quoting *Elrod v. Burns,* 427 U.S. 347, 373 (1976) (plurality opinion) (additional citations omitted).

IV. Conclusion

Carbolite appreciates this opportunity to share its views with FDA on this important subject. Carbolite supports reforms of nutrient content claim regulations that would authorize "anchored synonyms" and eliminate the need for term-by-term premarket clearance of such claims. Carbolite believes that FTC standards in this area provide useful guidance with respect to integrating First Amendment requirements in standards for claims. The agency's 1995 anchored synonym proposal took a significant, but ultimately inadequate step toward achieving the reforms the law requires. Carbolite believes that the further reforms necessary to satisfy First Amendment requirements would provide the greater flexibility that is needed for food manufacturers to communicate the nutrient content information consumers need and want in a clear, accurate, and effective manner.

Respectfully submitted,

Gerry Morrison /SR
Gerry Morrison
President
CARBOLITE FOODS, INC.
1325 Newton Avenue
Evansville, IN 47715
Tel: (800) 524-4473
Fax: (812) 485-0006
gmorrison@carborite.com

Sarah E. (Taylor) Roller
Sarah E. (Taylor) Roller, J.D., R.D., M.P.H
Miriam Guggenheim, Esq.
COVINGTON & BURLING
1201 Pennsylvania Ave., NW
Washington, DC 20004
Tel: (202) 662-6000
Fax: (202) 662-6291
sroller@cov.com
mguggenheim@cov.com

Counsel to the Petitioner,
Carbolite® Foods, Inc.