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PRESIDENT
NUTRITION DIVISION

January 7, 2003

Via Overnight Mail

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

**Re: Comment; Food Labeling: Nutrient Content Claims;
Implied Nutrient Content Claim in the Brand Name
Carbolite; Availability of Petition [Docket No. 02P-0462]**

Dear Sir/Madam:

Nestlé U.S.A., Inc. submits this comment in opposition to the above-referenced petition (the Petition) submitted by Carbolite Foods, Inc. (Carbolite Foods or the Petitioner). The Petition seeks a regulatory privilege well beyond that permitted by the brand name/implied claim petition regulation. The Petition fails to comply with the applicable legal requirements and use of "Carbolite" as requested by the Petitioner would result in misleading and deceptive labeling information. The regulatory requirements and goals set forth in the Nutrition Labeling and Education Act of 1990 (NLEA) dictate denial of the Petition by the agency.

I. SUMMARY

The Carbolite brand name is an implied nutrient content claim that conveys to the consumer that a product is "light" in "carbohydrates." Because the implied claim/brand name is not consistent with terms defined by the agency, and would be misleading, the Petition fails to satisfy the requirements of Section 403(r)(2)(A)(i). The Petition essentially seeks permission to use an entirely new nutrient content claim. The Petition should be denied and the Petitioner instructed that a novel "light in carbohydrate" claim should be submitted pursuant to Section 101.69(m) -- petitions for new nutrient content claims. 1/

1/ 21 C.F.R. § 101.69(m).

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II. PETITION FAILS TO SATISFY LEGAL STANDARD

A. Threshold Requirements

Central to the NLEA's purpose is that a claim "may be made only if the characterization of the level made in the claim uses terms that are defined by the Secretary." 2/ So-called nutrient content claims are defined as any claim "which expressly or by implication characterizes the level of any nutrient" 3/ A central goal of the NLEA was to ensure uniform meaning of defined nutrient content claims to avoid consumer deception that results when firms self-define claims.

Against this backdrop, Congress made an allowance for the use of a brand name that contains an implied nutrient content claim. The NLEA states that FDA shall permit use of a brand name containing an implied claim only if "the Secretary finds that such claim is not misleading *and is consistent with terms defined by the Secretary*" 4/ FDA's implementing regulations similarly state, in part, that a brand name petition identify the implied nutrient content claim, *the nutrient the claim is intended to characterize*, and the corresponding term for characterizing the level of such nutrient that has been approved by FDA. 5/

The Petitioner advances several legal theories to support its assertion that FDA should approve the Petition. For the purposes of this comment, we are not addressing the merits of these various assertions or whether the NLEA applies an "antideception standard" as portrayed by the Petitioner. Rather, the proper "standard" should amount to no more than application of the plain meaning of the NLEA requirements and the implementing regulation.

2/ 21 U.S.C. § 403(r)(2)(A).

3/ 21 U.S.C. § 403(r)(1)(B).

4/ 21 U.S.C. § 403(r)(H)(A)(iii) (emphasis added).

5/ 21 C.F.R. § 101.69 (o)(1) (emphasis added).

B. "Carbolite" Brand Name is Not Consistent with "Light" and "Carbohydrate" Definitions Adopted by FDA

The special allowance for brand name petitions does not give a petitioner the unfettered option to choose among the array of approved nutrient content claims. Rather, the regulation requires the petitioner to identify the implied claim contained within the brand name and "the nutrient the claim is intended to characterize." The Petition identifies "Carbolite" and argues that this implied claim is understood by consumers to connote a food product's sugar content.

The implied claim presented by the brand name "Carbolite" is derived from the plain meaning of the terms "carb" and "light" - - foods that contain a "light" amount of "carbohydrates." A "light in carbohydrate" nutrient content claim cannot be fairly viewed as characterizing the level of "sugar." "Sugar" is distinct and different than "carbohydrate" based on how each term is defined in the FDA food labeling regulations. Moreover, FDA has not approved use of "light" as a nutrient content claim characterizing the level of carbohydrates in a food.

The brand name petition process does not contemplate nor permit a petitioner to seek adoption of a brand name by relying on defined claims that convey a meaning markedly different from the implied claim in the brand name. Put simply, a "light in carbohydrate" claim cannot be reasonably viewed as consistent with, and intended to characterize, the level of "sugar" (e.g., "zero sugar," "reduced sugar"). Therefore, because of this obvious disconnect between the meaning of the implied "Carbolite" claim and existing FDA defined claims, we believe the Petitioner is wrong in relying on the distinct "sugar" claims as "regulatory benchmarks defining the Carbolite brand name." 6/

"Light" is rigorously defined by FDA according to strict criteria that cover only foods that are reduced in calories, fat and/or sodium. 7/ A review of the rulemaking record for "light" underscores the great care and substantial rulemaking record supporting FDA's final regulation governing use of "light"

6/ Petition at 9-10. The Petitioner concedes that FDA regulations currently do not authorize express nutrient content claims for "carbohydrate." *Id.* at 11.

7/ 21 C.F.R. § 101.5.

claims. Use of "Carbolite" as stated in the Petition conflicts with the FDA "light" regulation and favors use of a brand name that is misleading.

The threshold findings by the agency in defining "light" were substantial. The preamble accompanying the final rule states:

The agency concludes that it has sufficient information, including consumer surveys cited . . . and other information submitted in comments from which to establish an appropriate definition for the term. By defining "light" and the conditions for its use in a meaningful way, the agency intends to help alleviate the confusion caused by the many uses of the term and to ensure that products that bear the term are useful in maintaining healthy dietary practices. 8/

FDA cited substantial evidence that "light" is understood to connote reductions in calories and fat, thereby establishing requirements for each nutrient. Separate criteria were also adopted for a "light in sodium" claim.

The agency was well aware of the impact its policy would have on brand names. One comment suggested that a more liberal definition of "light" would minimize the number of brand names prohibited on the grounds that the foods do not qualify as "light." FDA rejected this comment, explaining: "'Light' is a term with special usefulness as a marketing tool for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in the level of fat or calories." 9/ The alternative which the commenter suggested (defining "light" in a fashion similar to "reduced" and "less" claims) was deemed inconsistent "with the special position of the term 'light' in the marketplace and with the strong impression that products labeled as 'light' are particularly useful in achieving a diet that is consistent with dietary guidelines as

8 58 Fed. Reg. at 2351.

9 *Id.* at 2353.

the available data and comments show.” 10/ Accordingly, “light” may be used to characterize the level of a nutrient only if the rigorous criteria set forth in the regulation are met.

Even if “Carbolite” were to mean “light in sugar” to some consumers instead of the obvious “light in carbohydrates,” FDA foreclosed the merit of the pending Petition in finding that “light” is not appropriate for characterizing the level of other nutrients, including “sugar.” Per the preamble: “The agency has determined that definitions of ‘light’ for nutrients other than calories, fat, and, on certain products, sodium would be misleading.” Noting that “light sugar” could perhaps serve as a useful nutrient content claim, the agency determined that “lacking any adequate justification for the term ‘light sugar,’ the agency is not convinced that such a definition should be established.” 11/

The Petition, of course, does not seek use of “Carbolite” in any fashion consistent with the “light” regulation. Most notably, the Carbolite line of products are marketed without any restrictions on the fat and caloric content of a food. Such disparate use of “light” in the context of carbohydrates would surely confuse consumers and create the very circumstance the NLEA was intended to remedy.

The implied “carbohydrate” portion of the “Carbolite” brand name raises issues similar to “light.” FDA has not defined claims that characterize the level of carbohydrates in a food. Accepting the Petitioner’s view that FDA did not consider the benefits of so-called low carbohydrate diets, it may well be appropriate for FDA to revisit these issues. It can only do so, pursuant to the NLEA, in

10 *Id.* The preamble discussion concludes: “Accordingly, the agency is not providing the same definitions for ‘reduced,’ ‘less,’ and ‘light.’”

11 *Id.* at 2359. It is possible that the Petitioner is of the view that its petition provides the rationale necessary to convince the agency that “light” should be permitted in terms of sugar content. If that is the case, the Petitioner should file a new petition seeking amendment to the “light” regulation. Only if FDA amends the “light” regulation could the pending brand name petition be fairly characterized as “consistent” with approved nutrient content claims as contemplated by the brand name petition requirements.

connection with a new nutrient content claim petition and rulemaking process. 12/ Granting exclusive rights to a "light in carbohydrate" claim through use of a proprietary brand name via the abbreviated brand name petition process would allow a result well beyond that contemplated by the plain meaning of the statute.

The Petitioner seeks to use a disclaimer in an apparent effort to address the fact that Carbolite products are not really "light." This is a curious position given that the Petition casts the NLEA treatment of nutrient content claims as employing an "antideception standard", yet the proposed disclaimer falls short of the FTC standard. The FTC generally disfavors the use of disclaimers and reliance on qualifying language to cure an otherwise misleading impression. 13/ In the present case, a false statement cannot be cured by a disclaimer. "Carbolite" products are not "light." 14/

12/ The NLEA provides for a streamlined brand name petition process precisely because the agency has already deliberated and reached conclusions about the underlying approved claim relied upon by the petitioner. The issues considered in adopting the "sugar free" and "reduced sugar" claims certainly did not encompass the "light in carbohydrate" claim implied by the "Carbolite" brand name. Indeed, as illustrated by the Petition itself, many nutrition science and health considerations underlining the "Carbolite" brand name were not considered by FDA. Against this backdrop, the assertion that "Carbolite" should be approved because the foods comply with defined claims for "sugar" is untenable.

13/ FTC has held that "[o]nce a misleading overall impression has been created ... explanations, disclaimers, or caveats are not likely to save the consumer from being misled. *In the Matter of MacMillan, Inc., et. al.*, 96 F.T.C. 208 (1980)(citing *Waltham Precision Instrument Co., Inc.*, 61 F.T.C. 1027, 1047 (1962), *aff'd*, 327 F.2d 427 (7th Cir.); *cert. denial*, 377 U.S. 992; *rehearing denied*, 379 U.S. 872 (1964)). See also *Crown Central Petroleum Corp.*, 84 F.T.C. 1493 (1974)("It is well-settled that where one of two meanings conveyed by an advertisement is false, the advertising is misleading.")

14/ It does not appear from the Petition that there are any requirements to ensure that the qualifying information is sufficiently prominent and immediately accompanies the brand name such that consumers would see or understand the information in the context of the "Carbolite" brand name.

The Petitioner adopted and now seeks to perpetuate a brand name that is inconsistent with FDA's nutrient content claim regulations and unlawful. It defies the plain language of the NLEA to conclude that a brand name that conveys an undefined nutrient content claim is somehow permitted when the terms that give the brand name meaning directly conflict with FDA's nutrient content claim regulations.

C. Petition Inconsistent with Sound Public Policy, Other Considerations

Beyond the legal bars to adoption of the purported brand name petition, the public policy issues at stake weigh heavily against FDA approval of the "Carbolite" brand name. The Petitioner introduces many intriguing concepts relating to "sugar carbs," "net effective carbs," and concepts promising weight loss. It may be possible to communicate these various notions of diet and health on the food label. ^{15/} However, the approval of a "light in carbohydrates" claim goes well beyond the bounds of the current regulations and should not be considered in connection with the brand name petition procedure. Rather, the Petition should be subject to the same scientific rigor and notice-and-comment rulemaking the NLEA dictates for all other new nutrient content claims.

The NLEA's petition process contemplates the filing of a petition in advance of the actual use of the brand name. Carbolite Foods elected to adopt and commercialize a brand name in complete disregard for the NLEA's nutrient content claim substantive regulations and required petition procedures. According to a June 20, 2001 Warning Letter, the maker of Carbolite products (Morico Foods, Inc.) was advised: "This product is misbranded because the label bears the nutrient content claim 'Carbolite' that is not authorized by regulation or the Act (Section 403(r)(1)(A)). FDA has defined the nutrient content claim 'Lite' by regulation. This definition does not extend to lite in carbohydrate." FDA's finding leaves little doubt that the "Carbolite" brand name is unlawful and not consistent with FDA's nutrient content claim regulations or the Act (Section 403(r)(1)(A)).

^{15/} Indeed, the Petition itself suggests means for communicating "net effective carbohydrate" – type information on the food label (e.g., "Carbohydrate Facts" box). See Petition at 14. Hence, it would appear that the food label can be used to communicate pertinent information in some fashion other than the misleading "Carbolite" brand name.

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The Petition represents the proverbial square peg that will not fit into the round hole. It is nonsensical to assert that a brand name that implies a "light in carbohydrate" message is consistent with FDA's nutrient content regulations when the foods bearing the "Carbolite" brand name in fact conflict with the "light" and related binding regulations. It is also a dubious proposition to assert that a "light in carbohydrate" claim would be viewed by consumers as merely characterizing the level of sugar in a food product. The NLEA rulemaking record contradicts this speculative notion. Far from serving consumer's need for accurate, reliable nutrition labeling information, the "Carbolite" brand name would mislead and therefore severely undermine the goals of the NLEA.

We respectfully request that when the Petition is denied, the agency consider what additional steps may be necessary to enforce this Warning Letter, issued more than 18 months ago.

Sincerely,



Ernie Strapazon
President, Nutrition Division
Nestlé USA, Inc.