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January 8, 2003

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

Re: Food Labeling: Nutrient Content Claims;  
Implied Nutrient Content Claim in the Brand  
Name CARBOLITE; Availability of Petition, 02P-0462

Dear Sir/Madam:

We are writing on behalf of Atkins Nutritionals, Inc. ("Atkins") to comment on the petition dated October 4, 2002 by Carbolite Foods, Inc. ("Carbolite") for the use of an implied nutrient content claim in their brand name, CARBOLITE.

Atkins believes that the relief sought in the petition should not be granted. Carbolite's tradename is not an *implied* nutrient content claim; it is an *expressed* nutrient content claim adopted for the purpose of characterizing the level of carbohydrates in the CARBOLITE products. The term can only mean that the products are "light" or "low" in carbohydrates.

Carbolite's petition requests that it be permitted to continue using its CARBOLITE brand name as an "implied nutrient content claim," even though FDA has not authorized any nutrient content claims, whether implied or express, for carbohydrates, and the term "light/lite" is not defined for carbohydrates. Carbolite filed this petition pursuant to a provision that permits companies to seek authorization to make implied nutrient content claims that have not been approved by the agency. Atkins believes that Carbolite must follow the course taken by the majority of similarly situated companies, which revised labeling to address certain of FDA's concerns.

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## POINT 1: CARBOLITE IS AN EXPRESSED, UNAUTHORIZED CLAIM

Carbolite argues that the CARBOLITE product line is intended as a "zero sugar" or "reduced sugar" food and that the use of the CARBOLITE term is "consistent" or "harmonized" with the regulatory scheme established by FDA on nutrient content claims. Therefore, Carbolite argues, it should be permitted as an implied claim in their brand name. However, CARBOLITE is an *explicit* -- not implied -- claim, about the level of *carbohydrates* -- not sugars -- in the products.

Carbolite suggests that the critical factor for consumers of Carbolite products is the correlation between sugar restriction and weight loss, which is dependent on controlling blood sugar levels rather than calories. In making this argument, Carbolite assures FDA that its products are "zero sugar" and "reduced sugar" foods. Those defined claims, therefore, are the ones available to the company as expressed, nutrient content claims for the CARBOLITE products. An implied claim about the *sugar* content of the product may also be appropriate in the brand name ("Sweet-n-low" or "Healthy Sweetness" are examples of implied claims in a brand names). Atkins does not believe that "CARBOLITE" is such a claim.

The terms "light" and "lite" are defined nutrient content claims which FDA has not authorized for use in the context of carbohydrates. 21 C.F.R. §101.56. The use of "light/lite" as applied to carbohydrates is the same in regulatory impact as claims such as "low carbohydrate" or "zero carbohydrates," all of which FDA has identified in industry Warning Letters or other documents as being unacceptable nutrient content claims for foods. Morico Foods, Inc., the company that marketed CARBOLITE in 2001, received a Warning Letter on June 20, 2001 stating that the nutrient content claim "CARBOLITE" is "not authorized by regulation or by the Act."<sup>1</sup>

Carbolite produced no consumer survey. Instead, it argues that its products are in fact *sugar* reduced products and that consumers somehow understand CARBOLITE to mean reduced or low in sugar. The petition acknowledges that sugars are but one element of the total carbohydrate figure as expressed on a product label. The company also acknowledges that the "net effective carbs" (undefined) figure is the important figure for those on "low carbohydrate weight loss diets". This underscores the fact that total carbohydrates, not just sugar, are what consumers focus on when purchasing these products. Carbolite's reference to Atkins in its petition is misplaced. The Atkins Nutritional Approach™ focuses on the broader carbohydrate figure, not the sugars sub-total.

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<sup>1</sup> Other companies, when notified of FDA's position on similar claims in brand names, made modifications to their names. For example, a product previously called Doctor's Diet Low Carb Bar is now called Doctor's CarbRite Diet, and a product previously called Lean Body Low Carb Bar is now called CarbWatchers Lean Body Bar.

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Carbolite should be seeking from FDA definitions for various functional carbohydrates and resulting carbohydrate nutrient content claims.<sup>2</sup>

POINT 2. THIS PETITION PROCESS SHOULD NOT BE AVAILABLE FOR  
CARBOLITE

When Congress passed NLEA, it provided a specific procedure for those seeking approval to make an implied nutrient content claim in brand names. This procedure allows for a 100-day time frame within which FDA must respond to the brand name petition. 21 U.S.C. 403(r)(4)(A)(iii). In the preamble to regulations implementing these statutory provisions, FDA stated that it understood that the "short time frame for brand name decisions is necessary in order to prevent inappropriate inhibition of production and marketing planning." FDA stated further that "given the need for such planning and the need to ensure that the consumer is protected, the agency recognizes the need for it to make decisions on implied nutrient content claims in brand names within the 100-day time frame." 56 Fed. Reg. 60421, November 27, 1991.

Clearly, FDA understood this time frame to be necessary *where a company was proposing a brand name but had not yet used that name in commercial marketing*. That situation does not exist. There is no reason to grant expedited treatment .

For the above mentioned reasons, Atkins respectfully requests that the relief sought in the Carbolite petition be denied in all respects.

Respectfully submitted,



Diane C. McEnroe

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<sup>2</sup> Relying on the health claim for dental caries, where FDA recognizes a category of "fermentable carbohydrates," Carbolite argues that *there are different classes of carbohydrates which are metabolically distinguishable from other carbohydrates*. This is the real issue for Carbolite, and one that FDA should be considering in the nutrient content claim context as well.