GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

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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:

Grocery Manufacturers of America, Inc., (GMA) appreciates the opportunity to comment on the above-referenced petition (the Petition) and urges the Food and Drug Administration to deny the petition. GMA has actively supported regulatory policies that allow for wide consumer access to nutrition and health information presented in a truthful and nonmisleading fashion. The Petition runs contrary to the requirements and spirit of the NLEA and should, therefore, not be approved in its present form as an implied nutrient content brand name petition.

GMA is the world's largest association of food, beverage, and consumer product companies. With U.S. sales of more than $450 billion, GMA members employ more than 2.5 million workers in all 50 states. GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues.

The NLEA was enacted to ensure access to truthful, non-misleading nutrition information from which consumers could make informed purchasing decisions. Accordingly, Congress mandated that so-called nutrient content claims be defined by FDA to reflect sound dietary guidelines and to

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establish consistent meaning and use of these terms when used to characterize the level of a nutrient in a food.

The petition process allows for the approval of a brand name that implies a nutrient content claim if the brand name is not misleading and consistent with the nutrient content claims defined by FDA. Specifically, the petition must identify the claim implied by the brand name, the nutrient the claim is intended to characterize and the corresponding claim that characterizes the nutrient that has been approved by FDA. The Petition fails to satisfy these threshold requirements.

"Carbolite" implies that a food is "light" (or "lite") in "carbohydrates." This meaning is inescapable as it is derived by the reasonable consumer directly from the plain meaning of the brand name. The nutrient level characterized relates to carbohydrate content of a food. The Petition offers a different view, asserting that "Carbolite" conveys a "no sugar" or "reduced sugar" claim. On this basis, the Petition states that "Carbolite" is consistent with FDA defined nutrient content claims. This preferred interpretation of the "Carbolite" brand name is at odds with its plain meaning.

A consumer would reasonably conclude that a "Carbolite" branded product is "light" (i.e., it contains reduced levels of calories, fat and/or sodium as defined by FDA). This is, of course, not the case. The regulatory history underlying adoption of the "light" regulation reflects FDA's view that "light" connotes substantial reductions in calories and fat. The agency declined to permit use of "light" to characterize other nutrients on this basis. It appears from the Petition that there are no restrictions placed on the levels of calories and fat of "Carbolite" products. This complete failure to satisfy the "light" requirements results in a misleading brand name which is, therefore, ineligible for approval through the abbreviated brand name petition process.

Significantly, the agency has not adopted a regulation authorizing a "light" or other claim that characterizes the level of carbohydrates in a food. If a firm wanted to make a "light in carbohydrate" or similar claim, the NLEA requires that a petition for a new claim which triggers notice-and-comment rulemaking. Allowance of the "Carbolite" brand name effectively grants, for the first time, FDA approval of a "light in carbohydrate claim." The NLEA petition procedures do not contemplate nor permit use of the brand name petition process for a new claim.

There are sound reasons, beyond the letter of the law, for why FDA should deny the Petition. Granting the Petition would provide the petitioner with exclusive rights to its implied "light in carbohydrate" claim. At the same time, all other food marketers would be prohibited from similarly communicating information on the label that characterizes the level of carbohydrates in a food. That is, other companies that sought to position products as "light in carbohydrates" would remain in violation of the law. This result was surely not the intended consequence of the NLEA's limited treatment of brand names that imply a claim consistent with nutrient content claims adopted by FDA.

The streamlined, 100-day brand name petition process is, by its very nature, not a suitable process for establishing a new nutrient content claim. The Petition observes that FDA did not consider many key aspects of nutrition science that are said to underscore the value of the "Carbolite" brand name, namely "the alternative construct that forms the basis for low carbohydrate weight loss diets, which restrict only *net effective carbs.*" Petition at 20 (emphasis in original). Precisely because FDA did not consider these nutrition concepts in establishing the current nutrient content claim regulations, "Carbolite" should not be authorized pursuant to the implied claim/brand name petition regulation.

The Petition in its present form must be denied as it extends well-beyond the legal bounds constructed for the approval of a brand name that conveys an implied claim. Use of "Carbolite" as proposed is entirely inconsistent with the nutrient content claim regulations and would surely mislead consumers as to the nature and level of the nutrients bearing the "Carbolite" brand name.

Sincerely,

Alison J. Kretser

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Director, Scientific and Nutrition Policy