



November 19, 2004

Linda F. Golodner
President
National Consumers League
1701 K Street, NW
Suite 1200
Washington, DC 20006

Dear Ms. Golodner:

This is in response to your October 7 letter to the Food and Drug Administration (FDA) about carbohydrate-related statements and claims used in food labeling.

FDA shares your concern with the proliferation of carbohydrate labeling claims and statements currently being used in the marketplace. As you may be aware, FDA has received several petitions from industry on the use of carbohydrate content claims and related statements in food labeling. FDA completed its review of these petitions and the comments received and expects to initiate rulemaking in response to these petitions.

One of the issues the agency is particularly interested in is the consumers' perception of "low carbohydrate" foods in relation to weight control. The agency is interested in consumer research data or other factual information on this issue and requests that you provide us a copy of the Opinion Research Corporation survey and results that you cited in your letter. We encourage you to provide comments on our proposed amendments when the proposed rule is published in the *Federal Register*. We have forwarded your letter to our Dockets Management for inclusion in Docket No. 2004N-0501. Please be assured that we will consider all comments received before making a final decision on this issue.

With respect to "net carbohydrate" labeling, although FDA has not issued guidance regarding the use of such statements, the agency has not generally objected to the use of "net carbohydrate" type information on food labels if the label adequately explains how the terms are used so that it would not be false or misleading to consumers. If FDA determines that such statements or their explanations are false or misleading, we will take appropriate action. FDA also expects to address this issue in its rulemaking on carbohydrate labeling.

FDA has taken enforcement action against products that misrepresent themselves as "low" or "reduced" in carbohydrate. For example, the agency notified a manufacturer that its products bearing a "low carb" claim are misbranded under section 403(a)(1) of the

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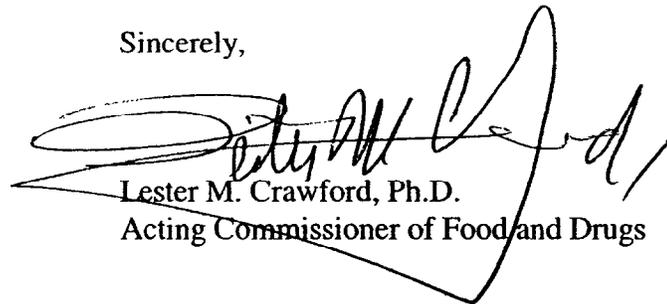
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Federal Food, Drug, and Cosmetic Act. FDA determined that the “low carb” claim is false and misleading because a comparison of the carbohydrate content of the products to comparable products revealed that they contain the same or similar amounts of carbohydrate (see FDA warning letter dated January 22, 2004, to Russell Stover Candies, Inc. (http://www.fda.gov/foi/warning_letters/g4705d.htm)). We will continue to pursue action against products that are similarly false and misleading. If you have specific information about foods currently in the marketplace that you believe carry false or misleading carbohydrate content claims, please submit the labels and any supporting information to us for review and appropriate follow-up action.

Thank you for your interest in this issue. I hope this information is helpful. If I may be of further assistance, please let me know.

Sincerely,



Lester M. Crawford, Ph.D.
Acting Commissioner of Food and Drugs

Copy to:

Mr. J. Howard Beales III
Director
Bureau of Consumer Protection
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580