Owens, Shirelle

From: Owens, Shirelle
Sent: Monday, June 28, 2004 3:26 PM
To: Owens, Shirelle
Subject: BFDRMS REPORT SENT TO EMAIL

PROJECT: 88763 OFSAN EXECUTIVE CORRESPONDENCE OFFICE: CNPIDS
OL/EXEC SEC NUM: 04 3609 LEVEL:

DATE OF DOCUMENT: 2004/06/22 DATE RECEIVED: 2004/06/28 DATE DUE: / /
DATE DONE: / /

FROM: LEE SANDERS, VICE PRESIDENT, REGULATORY & TECHNICAL SERVICES, & PAUL C. ABENANTE, PRESIDENT & CEO, AMERICAN BAKERS ASSOCIATION (ABA), WASHINGTON, DC. 20005-3305, FDA TRAC. NO. 04 3609

SUBJECT: RE: DEFINITION OF CARBOHYDRATE RELATED NUTRIENT CONTENT CLAIMS AND NET CARBOHYDRATE LABELING FOR FOOD PRODUCTS.

ACTION: (X) PREPARE DIRECT REPLY

INSTRUCTIONS: PLEASE RESPOND IF NECESSARY, AND CLOSE OUT OF CTS UPON COMPLETION. FORWARD A COPY OF YOUR RESPONSE TO HFS-22CCO S. OWENS/R. WHEELER & K. MALONE, HF-40. IF YOUR OFFICE CHOOSES NOT TO RESPOND, PLEASE CLOSE OUT IN CTS INDICATING "NO RESPONSE NECESSARY".

COMMENTS: COPY TO: EOS PENDING FILE

SENT TO	SENT FROM	DATE SENT	ASSIGNED
HFS-800	HFS-22CCO	06/28/2004	

ROUTING SLIP
GENERATED BY: HF-40
DATE: JUN 28, 2004

FDA CONTROL NUMBER: 04 3609 **TRACER #:** **OS #:**

DATE OF CORRESPONDENCE: 06/22/04 **DATE INTO FDA:** 06/25/04

TO: LESTER M CRAWFORD, ACTING COMMISSIONER OF FOOD AND DRUGS
ROBERT E BRACKETT., PH.D., FDA - CFSAN

FROM: LEE SANDERS, ABA, AMERICAN BAKERS ASSOCIATION
PAUL C ABENANTE, ABA, AMERICAN BAKERS ASSOCIATION

SYNOPSIS: WRITES CONCERNING THE DEFINITION OF CARBOHYDRATE RELATED NUTRIENT CONTENT CLAIMS AND NET CARBOHYDRATE LABELING FOR FOOD PRODUCTS; REF: TRAC # 04-3227.

LEAD OFFICE: HFS-1 **HOME OFFICE:** HF-40

CONTACT/PHONE#: KELLY M MALONE 301-827-4437

COPIES: GENERAL DISTRIBUTION
HF-1 LESTER M CRAWFORD
HF-40 INDYA G MUNGO

COORDINATION:

SIGNATURE REQUIRED:

REFERRALS FROM HF-40

ASSIGNED TO	ACTION	DUE DATE
HFS-1	NECESSARY ACTION	

American Bakers Association

Serving the Baking Industry Since 1897

June 22, 2004

Lester Crawford, DVM, Ph.D. (HF-1)
Acting Commissioner
Food and Drug Administration
Room 14-71
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Robert E. Brackett, Ph.D. (HFS-1)
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Definition of Carbohydrate Related Nutrient Content Claims and Net Carbohydrate Labeling for Food Products

Dear Dr. Crawford and Dr. Brackett:

The purpose of this letter is to voice the American Bakers Association (ABA), views regarding the definition of carbohydrate related nutrient content claims, as well as, guidance to industry on net carbohydrate labeling.

ABA is the national trade association representing the wholesale baking industry and our membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States.

The National Academy of Sciences, Institute of Medicine, recently recommended that 45-65 percent of daily calories should come from carbohydrates, and currently there is an approximate average US consumption of 52% in the diet. Further, the World Health Organization recommended that 55-75% of calories consumed daily should come from

04-31-09

carbohydrates. ABA believes that establishment of nutrient content claims for free, low and reduced carbohydrate claims could be misleading to consumers, making them wrongly think that carbohydrates are not healthy. The baking industry is concerned that without proper educational explanation and communication to consumers accompanying any new guidance on such claims, consumers could be led to make uneducated and potentially unhealthy food choices.

Nonetheless, if FDA decides to proceed with guidance, ABA would support the specific approaches that are outlined below. ABA has reviewed and discussed in detail with its membership the various citizens' petitions that have been submitted to the Agency with regard to definition of carbohydrate related nutrient content claims and has also explored additional alternatives. ABA believes it is important to share with the agency the baking industry's views on the various proposed claims since they would impact the baked product category.

Nutrient Content Claim Definitions

ABA agrees with the recommendations of the Grocery Manufacturers of America (GMA) and Kraft Foods on their definition for free and reduced/less definitions:

Carbohydrate free: Defined as less than 0.5 gram per serving and per reference amount customarily consumed (RACC) for individual foods

Reduced/less: Defined as at least a 25% reduction; this would confirm FDA's current authorization of relative claims 21 CFR§101.13

ABA supports the GMA proposed definition for low carbohydrates because it is grounded on sound science:

Low Carbohydrate: Defined as 9 grams of carbohydrate or less per reference amount customarily consumer (RACC) for individual foods

Additionally, ABA believes that based on the average 2000 calorie diet, where approximately 50% of calories should come from carbohydrates, the definitions for excellent and good sources of carbohydrates should correlate with those current government recommendations.

The USDA/HHS Food Guide Pyramid and Dietary Guidelines for Americans recommends 15 to 26 servings of food a day for consumers. With a minimum of the recommended 15 servings per day of food, to achieve a diet of 300 grams of carbs per day, it would require that each serving contribute 20 grams of carbs. People will eat a variety of foods, including low, good and excellent sources of carbohydrates. If consumers eat a balanced mix of low, good and excellent sources of carbohydrates, then defined as 9, 20 and 40 respectively, yields the required 300 grams of carbohydrates per day.

ABA believes that through this scenario, there is an even distribution spread between the nutrient content claims for low, good and excellent sources for carbohydrates that is logical and would be beneficial to consumers. As Kraft points out in their petition, it is unrealistic to define 'excellent' as 20% of the DV (approx 300 grams) as there are no foods that deliver 60 grams of carbohydrates per serving. Lastly, ABA recommends that foods that are more than 30% simple sugar should not be permitted to use the good and excellent source claims.

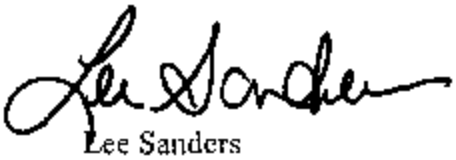
> Excellent Source: should be defined as 40 grams per reference amount customarily consumed (RACC) for individual foods; which is approximately 20 percent of recommended daily carbohydrate intake
>
> Good Source: should be defined as 20 grams per reference amount customarily consumed (RACC) for individual foods; which is approximately 10 percent of recommended daily carbohydrate intake

Net Carbohydrate Statement

With regards to net carbohydrate language on food product labeling, ABA agrees with the statement that was submitted by the Grocery Manufacturers of America (GMA). Like GMA, ABA concurs with the central thesis of the Agency's obesity report that "Calories Count", and therefore, ABA supports a recommendation that any declaration of the net carbohydrate content on the principal display panel of a food, except a food that meets the FDA definition for low calorie, be directly accompanied by a prominent declaration either of the calories per serving (as declared in the Nutrition Facts box), or of a prominent statement that refers to the Nutrition Facts box for calorie information, or of a prominent statement that otherwise refers to the importance of calories. This approach reinforces the importance of calories in both weight maintenance and reduction.

ABA appreciates this opportunity to comment to FDA on this the issue of carbohydrate nutrient content claims and net carbohydrate statements and looks forward to working with FDA on its impending draft guidance regarding net carbohydrate labeling.

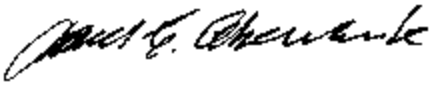
Sincerely yours,



Lee Sanders

Vice President

Regulatory & Technical Services



Paul C. Abenante

President & CEO