



International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association

January 17, 2006

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

**Docket No. 2005N-0413: Assessing Consumer Perceptions of Health Claims;
Public Meeting; Request for Comments**

To Whom It May Concern:

The International Dairy Foods Association (IDFA) appreciates the opportunity to comment on consumer perceptions of qualified health claims and the recent FDA Working Paper, "Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims." These comments are submitted on behalf of IDFA and its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute. The 500 member companies of these associations represent processing and manufacturing facilities and their suppliers, and account for about 85% of the dairy products consumed in the United States.

The dairy industry is proud of the healthful products we make available to our consumers. We want to be able to provide our customers with the most accurate information possible about the health benefits of our products. We provide the following comments in order to help qualified health claims present the clearest health information to consumers.

Four Tier Scheme

IDFA believes that the weight of the scientific evidence in support of a particular claim will not always fit into the four-category scheme as proposed and currently used by FDA. Consequently, standardized qualifying language cannot be applied rigidly by FDA for an entire category of qualified health claims for several important reasons. First, the First Amendment to the United States Constitution requires that FDA permit the use of any explanatory or qualifying terms that accurately convey the weight of the scientific evidence and are not misleading. Second, where the weight of the scientific evidence falls midway between any two of the FDA categories, it will be necessary to fashion

appropriate qualifying language that reflects the weight of the scientific evidence rather than just using the standard phrases set forth by FDA in the interim guidance. The focus must always be on conveying accurate, truthful and non-misleading information to the consumer and not upon the use of some standardized terminology offered by FDA. The standardized qualifying language might serve as one option for petitioners, but FDA should allow different terminology that is consistent with the scientific evidence. This is particularly relevant when the petitioner supplies consumer survey data demonstrating that the proposed claim and qualifying language meets the FDA "reasonable person" standard.

Studies of Generic Claims

IDFA commends FDA's commitment to testing consumer perception and reaction to qualified health claims and methods for declaring the scientific support of these claims. However, we believe that FDA cannot rely on tests of generic label copy concerning hypothetical products, brands, and marketing contexts to meet its obligations related to the First Amendment or public health. We believe FDA lacks the authority to shift its case-specific burden of proof to food marketers through a rulemaking process that relies on generic hypothetical data. In addition, IDFA anticipates that any attempt to codify health claim restrictions in regulations based on findings from generic copy tests would be readily subject to challenge under the First Amendment.

The determination concerning what constitutes the "end perception" consumers take away from a particular claim cannot be evaluated in a scientifically valid or reliable manner through academic research that attempts to isolate the meaning of health claims from the particular product, brands and dynamic consumer beliefs and knowledge that form the context for health claims used under real marketing conditions. FDA's working paper indicated that consumers' prior beliefs about a disease-substance relationship may have caused them to react differently to tested health claims. However, the effect and magnitude of the effect of consumers' prior beliefs is unknown. Moreover, even if the FDA study generated findings that are meaningful for academic purposes in the context of the hypothetical product-claim combinations, such findings would have no scientific validity or meaning in the context of these or other product-claim combinations presented under real world conditions at other times or in other contexts.

IDFA believes that for FDA health claim policies to fully benefit public health, FDA must focus energies not merely on ensuring that formulaic health claims expressions are supported by nutritional science, but also must ensure that substantiated diet/health information can be expressed in the ways that are most effective in connecting with consumers and motivating healthful food purchasing and consumption decisions. Consumers ultimately must choose between food products as well as brands - in a market place where health benefit claims must compete alongside claims for taste, convenience, price and fun.

Consumer Research Results

In consumer research by both FDA and the International Food Information Council (IFIC), consumers' responses indicated that they had difficulty understanding the strength of the science behind qualified health claims. Often, the language provided to explain the strength of science behind a claim was not clear enough to allow consumers to differentiate between claims with different levels of scientific basis. In addition, some research showed that qualifying language at the "B" or "C" levels actually made the claims and products more appealing to consumers than unqualified health claims and products that displayed them. We agree with FDA's conclusion that "none of the different ways tested to communicate the strength of science supporting a food label health claim performed very satisfactorily."

While the report card letter graphic did seem to help consumers understand the amount of scientific evidence backing up a health claim, a disturbing effect of this type of graphic was that consumers felt that the grade given to the science also applied to the quality, healthfulness and safety of the product making the health claim. For example, a product making a "C" level claim with the accompanying graphic may cause a consumer to believe that the product is not of high quality, safety or healthfulness. Consumers may choose a different food that could be a less healthful choice, resulting in an action that is in direct opposition to the intent of the health claim and of FDA's Consumer Health Information for Better Nutrition Initiative.

Report card-type grading systems are used in many states to rate the sanitation and safety of restaurants, so it is not surprising that consumers would also believe that a grade on a food label would indicate the safety of the food inside the package. Since the report card graphic impacted consumer perceptions of food safety, a grade other than "A" could lead a consumer to believe that the food product is not as safe as it could be. Since FDA strictly regulates the safety of the food sold to American consumers, especially through cooperative programs like the Grade "A" PMO, consumer belief that one food is not as safe as possible could also lead to a belief that all food regulated by FDA is not safe.

In summary, the results of the consumer testing by FDA and by the International Food Information Council have demonstrated that qualified health claims using standardized qualifying language and/or graphics are not effective at communicating health messages to consumers. Many statements about a disease-substance relationship will not easily fit into the four category system as proposed by FDA. In addition to the initial problem of categorizing a qualified health claim, there are also problems with requiring these statements to use pre-set qualifying language or graphics which do not give consumers an accurate picture of the science behind the claim and the product's overall healthfulness, safety and quality. However, IDFA believes that in keeping with FDA's Consumer Health Information for Better Nutrition Initiative, consumers should be given more information about the health and nutrition benefits of the foods they consume so that they can make better informed decisions. This information should be allowed to be provided in whatever manner is appropriate and clear to that product's consumers. The method of

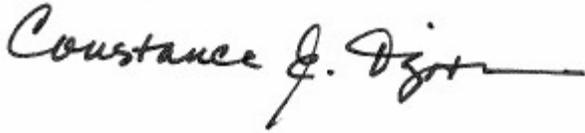
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declaration and the method of qualifying the supporting science supporting may be different for each claim.

Qualified health claims that are clear to consumers should be allowed on food labels and labeling. However, since each product, package and disease-substance relationship is different, these qualified health claims cannot be forced to fit into a four tier scheme with standardized qualifying information. The dairy industry looks forward to providing consumers healthy products labeled with accurate and effective health information.

Respectfully Submitted,

A handwritten signature in cursive script that reads "Constance E. Tipton". The signature is written in black ink and includes a horizontal line at the end.

Constance E. Tipton
President and CEO

A handwritten signature in cursive script that reads "Michelle Albee Matto". The signature is written in black ink.

Michelle Albee Matto, MPH, RD
Manager, Regulatory Affairs