International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

February 8, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Via Electronic Submissions: http://www.fda.gov/dockets/ecomments

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of Health Claims on Food Packages; NOTICE. [FDA Docket No. 2004N-0486] (69 Fed. Reg. 71819 (December 10, 2004)).

Dear Sir/Madam:

These comments are submitted on behalf of the International Dairy Foods Association (IDFA), the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and suppliers. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). IDFA's 500-plus members range from large multinational corporations to single-plant operations and represent more than 85% of the total volume of milk, cultured products, cheese, and ice cream and frozen desserts produced and marketed in the United States.

IDFA's top priorities include addressing issues relating to the effective marketing of dairy products for consumption as part of a healthy diet. In this regard, IDFA administers a wide variety of research, education, training, and generic marketing programs to assist its members in their individual marketing programs. IDFA also manages generic marketing programs sponsored by the National "Got Milk?" Milk Mustache Campaign under the direction of the Milk Processor Education Board. IDFA is pleased to have this opportunity to comment on the consumer research and related policy matters in the above-referenced FDA docket.

FDA policies concerning the use of labeling claims aimed at communicating the nutrition and health benefits of food products are of vital concern to IDFA and its members. Dairy products face an increasingly competitive marketing environment with other foods and beverages. This has been particularly true in the milk category, which has suffered per capita declines in consumption over the past 30 years. The competitive marketing environment not only presents economic challenges for IDFA members, but also provides opportunities to impact public health. As reflected in the recently issued recommendations of the 2005 Dietary

Guidelines, an expanding body of scientific research provides strong support for the health promotion and disease prevention benefits for the nation that are associated with achieving adequate levels of dairy product consumption. While national dietary guidance issued by the government, including the 2005 Dietary Guidelines, is critically important for promoting public health, substantially greater gains can be made through the much broader dissemination of such information by appropriate health claims in food labeling and other commercial marketing materials.

Throughout the challenging history of FDA health claims policy, agency priorities have emphasized the need for health claims that are supported by appropriate scientific evidence, and maintaining FDA control over the specific language formulations prescribed to express health claim messages. These historical priorities have yielded disappointments and missed opportunities for promoting public health, and inadequate protections for commercial speech under the First Amendment.

While IDFA commends FDA's recent commitment to implementing health claim policy reforms, and recognition of the importance of consumer research, the current FDA research proposal presents several serious and fundamental concerns and should be abandoned.

First, the manner in which FDA has articulated the role and relevance of consumer research to health claim regulatory matters suggests that the agency is misconstruing its legal authority under the applicable First Amendment standards. Under the First Amendment, FDA has the burden of proof to justify regulatory restrictions it seeks to impose on the expression of any particular health claim. The agency's burden of proof requires that the agency have evidence establishing that any alleged harms attributed to specific health claims are "real" - precluding restrictions based on harms that are based on mere speculation or conjecture. In addition, the agency's burden of proof requires FDA to establish that the restrictions it would impose on the freedom of health claim expression, in fact, function to alleviate the documented harms to a material degree. The agency's legal obligations in this regard are case-specific, as would arise in the context of an enforcement action taken against a particular marketer with respect to a particular health claim expression.

FDA cannot rely on generic copy tests concerning hypothetical products, brands, and marketing contexts to carry its burden of proof with respect to actual claims made for specific products, brands, and directed to particular consumers. In addition, IDFA anticipates that any FDA 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. In summary, 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.

Second, IDFA believes the particular health claim research FDA proposes to undertake is scientifically flawed and cannot yield results that are capable of informing FDA policy reforms in the ways that are necessary to make genuine public health gains. The agency represents that the proposed research is intended to "enhance FDA's understanding of consumer responses to

health claims and inform any policy initiative(s) that FDA may undertake in the future to provide consumers with information to help them make informed food choices." We do not believe flawed research can be useful in informing policies applicable to a broad array of food products, claims, and market conditions.

Third, 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 products, brands, and dynamic consumer beliefs and knowledge that form the context for health claims used under real marketing conditions. Moreover, even if the proposed FDA study were capable of generating findings that were meaningful for academic purposes in the context of the proposed hypothetical product-claim combinations at the time the research was conducted, 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.

Finally, we believe that for FDA health claim policies to fully benefit public health, FDA must focus energies not merely on ensuring that formulaic health claim 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 marketplace where health benefit claims must compete alongside claims for taste, convenience, price, and fun.

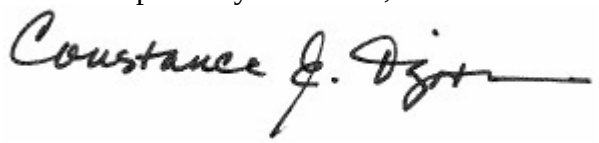
The kind of consumer research that is required for food marketers to be successful must discover how best to express substantiated health benefit information in ways that are genuinely relevant and motivating to consumers in the context of the food choices and eating occasions they confront and which all add up to dietary patterns that either do well, or could do much better in promoting health and preventing disease. We believe this can be accomplished only through very product specific and message specific research.

Generic copy tests of the kind FDA proposes would be unproductive and present a danger that misinformation will be codified in new health claim policies that are counterproductive.

In the judgment of IDFA, expanding FDA openness to the knowledge, experience, and expertise of professionals outside the agency who specialize in consumer research of the kind necessary for effective food marketing offers the greatest opportunities for promoting the public health through FDA health claim policy.

For the foregoing reasons, IDFA respectfully opposes the health claim research proposed by FDA, and urges the agency to abandon the proposal.

Respectfully submitted,



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cc: C. Frye, C. Hough, T. Nagle