

February 24, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1060
Rockville, MD 20952

Submitted electronically to fdadockets@oc.fda.gov

Re: Docket No. 2003N-0496, "Food Labeling: Health Claims; Dietary Guidance"

Dear Sir or Madam:

The International Dairy Foods Association (IDFA) appreciates the opportunity to provide comments in response to the advance notice of proposed rulemaking (ANPR) that the Food and Drug Administration (FDA) published on November 25, 2003 to address health claims and dietary guidance for conventional food and dietary supplements.

IDFA, which represents the nation's dairy processing and manufacturing industries and their suppliers, is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). Its 500-plus members range from large multinational corporations to single-plant operations, representing more than 85% of the volume of milk, cultured

products, cheese, ice cream and frozen desserts produced and marketed in the United States-- an estimated \$70 billion a year industry.

IDFA is a member of the Grocery Manufacturers of America's Coalition that had previously submitted comments to FDA on May 4, 2003 and January 20, 2004 in response to this ANPR. IDFA fully supports the earlier comments presented by the Coalition. However, IDFA wishes to provide additional comments on selected sections of the ANPR related to regulating qualified health claims in the labeling of conventional foods and dietary supplements and on the appropriateness and nature of dietary guidance statements.

I. Health Claims

A. Regulatory Alternative for Qualified Health Claims

FDA is considering three alternatives (i.e. options) identified in the report by the Task Force on Consumer Health Information for Better Nutrition (the Task Force) for regulating health claims that do not meet the “significant scientific agreement” (SSA) standard of evidence (i.e. qualified health claims) required in 21 CFR 101.14(c) to evaluate the scientific validity of health claims. The options being considered are: Option 1 – incorporate the interim procedures and evidence-based ranking system into a regulation under notice-and-comment rulemaking; Option 2 – reinterpret the SSA standard to apply to the accuracy of the characterization of the evidence supporting the claim and require each qualified health claim to undergo notice-and-comment rulemaking similar to the process for health claims for conventional foods; and Option 3 – treat

qualified health claims as wholly outside the Nutrition Labeling Education Act (NLEA) and regulate them solely on a postmarket basis, if they are false or misleading.

IDFA strongly supports the prenotification process that FDA has been using in its interim procedures and evidence-based ranking system for evaluating qualified health claims and urges the FDA to retain this overall approach with specific modifications suggested below:

1. IDFA believes that the filing of a qualified health claim premarket notification should be published as a Federal Register notice that provides time for technical review and public comment, and that the final FDA determination of premarket notification should also be published in the Federal Register. Additional information would also be appropriate for posting on the FDA website. IDFA believes that the Federal Register publication of the filing of the premarket notification and the final decision on the qualified health claim petition will ensure the most widespread public notice.
2. IDFA believes that the weight of the scientific evidence in support of a particular claim will not always fit into the four-category Evidence-Based Ranking scheme as proposed by FDA. Consequently, the standardized qualifying language suggested in the interim guidance procedures as appropriate for a particular

category of qualified health claim cannot be applied rigidly by FDA 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 suggested by FDA in the interim guidance might serve as one option for petitioners submitting premarket notification, but FDA should allow different terminology that is consistent with the scientific evidence. This is particularly relevant when the premarket notification contains consumer survey data demonstrating the proposed claim and qualifying language meets the FDA "reasonable person" standard.

3. IDFA believes that the letter grading system that FDA proposes to assign to qualified health claims, based upon the level of scientific evidence supporting them, is likely to confuse rather than inform consumers. Consumers will very likely interpret these grades as indicative of the health value or overall quality of the food product, rather than the level of scientific evidence supporting the claim.

IDFA is concerned that such confusion will discourage companies from petitioning FDA for use of a qualified health claim. Therefore, IDFA strongly urges FDA to eliminate the letter grade designations it has proposed, and recognize the constitutional right of companies to develop equivalent alternatives to the agency's model qualifying language. IDFA is concerned that if the existing ranking system remains in place, it threatens to undermine the value of the information that it seeks to promote. IDFA also believes that the interim procedures should also be clarified to emphasize that the focus of any rating system must be on the weight of the scientific evidence in support of the specific proposed claim.

In summary, IDFA strongly opposes Option 2 because it would require each qualified health claim petition to undergo notice-and-comment rulemaking and would require excessive FDA and industry resources resulting in unwarranted excessive delays of up to 540 days to communicate important health information to consumers.

Additionally, although Option 3 to regulate claims solely on a post market basis seems like a simple approach similar to the FTC regulations for advertising claims, IDFA does not fully support this concept. IDFA believes that if modified as proposed, Option 1 would represent the best means of promoting communication of truthful, accurate, and non-misleading qualified health claims.

B. Issues Raised in the Task Force Report

In its report, the Task Force recommended that FDA seek comment on several additional topics related to health claims.

1. Revised Claim Language for Unqualified Health Claims

FDA regulations require SSA health claims to state that the substance “may” reduce the risk of the specified disease or health related condition. IDFA agrees with FDA that the word “may” leads to uncertainty about the science behind the claim because, as noted by FDA, consumers are likely to interpret the word “may” as “a reflection of the science supporting the claim rather than the certainty about the ability of a dietary practice to affect any one consumer.” IDFA strongly supports the Task Force’s suggestion to remove the qualifier “may” from unqualified health claims so that the uncertainty surrounding claims such as “calcium may reduce the risk of osteoporosis” is eliminated.

2. Interim Final Rules (IFRs) for Unqualified Health Claims

The Task Force recommended that FDA solicit comments on whether FDA should authorize unqualified health claims through IFRs to expedite the availability health claims in food labeling. FDA reliance upon interim final rules (IFRs) for unqualified health claims has been essential to promoting enhanced communication regarding the health benefits of food. IDFA urges FDA to continue use of IFRs to expedite the availability of all health claims.

3. Evaluations of Outside Scientific Groups

IDFA urges FDA to consider the findings, conclusions, and recommendations of outside scientific groups for making important contributions to understanding the

relationship between diet and health or disease. The scientific value and credibility of contributions made by outside scientific groups should be evaluated on the basis of standard scientific criteria -- the training and expertise of the individuals involved, the thoroughness of the evaluation that they have undertaken, the quality of the report they have produced, the scientific data and information on which they rely, and other similar factors. In short, each recommendation of an outside scientific group must be evaluated on the merits of the work, not on the general merits of the organization.

4. Competent and Reliable Scientific Evidence

IDFA agrees with the Task Force's recommendation that "competent and reliable scientific evidence" as defined by FTC is appropriate when applied to qualified health claims. IDFA recommends that the standard of credible scientific evidence can be satisfied by any scientific study that meets long-established principles of scientific investigation, *e.g.*, a written protocol that describes the investigation in adequate detail, informed consent of study subjects, documented methodology, statistical analysis of results, and a written report reviewing the investigation and containing its conclusion. Such evidence may include *in vitro* data, results of animal experimentation, data on the mechanism of action involved in any nutrient-disease relationship, epidemiology, clinical studies and any other form of scientific information. The evidence need not be published or peer-reviewed, and the results of consumer testing could be considered as part of the supporting information. The

specific wording of the claim would determine the type and quantity of evidence required to support it.

II. Dietary Guidance

The Task Force recommended that FDA also seek opportunities to promote the development and use of more dietary guidance statements on foods in order to assist and encourage Americans to make better food choices and establish healthier eating patterns. FDA acknowledges the importance of dietary guidance statements and points out that these types of statements are not health claims. Dietary guidance statements can be made for conventional food without FDA review or authorization but like all food labeling statements must be truthful and not misleading. Accordingly, FDA has recognized the need to identify and agree upon dietary guidance that is appropriate for food labels and how such guidance may be used.

A. Regulatory Distinctions Between Dietary Guidance and Health Claims

IDFA agrees with FDA's distinction between health claims and dietary guidance statements as noted in the ANPR which indicated that "Unlike health claims, which target a specific substance and a specific disease or health-related condition, dietary guidance statements focus instead on general dietary patterns, practices, and recommendations that promote health." FDA also noted that dietary guidance statements may make reference to a disease or substance, but not both. IDFA believes, however, that these criteria cannot be imposed in such a rigid manner as indicated in the preamble to the final rule regulating health claims for conventional foods. IDFA believes companies should have the right to

make dietary guidance statements that make reference to both a disease and a substance. Claims related to reduced risk of a specific disease or a health related condition should be permitted to communicate the general nutritional significance of the foods or food groups associated with that dietary pattern, as these statements would not necessarily trigger health claim status if such statements are truthful, accurate, and nonmisleading

B. Issues Relating to Dietary Guidance

1. Definitions

IDFA agrees in principle with the current FDA distinction between a health claim and dietary guidance with generic modifications that address the example noted in part above. IDFA asserts that FDA does not have the authority to review or authorize dietary guidance statements before use. Additionally, where relevant, dietary guidance should be allowed for either a broad food category of food such as milk and dairy products or also a specific substance such as calcium. Broadening the scope of dietary guidance statements is important because the purpose of these statements is to inform consumers on healthy food choices and which foods provide specific beneficial substances.

2. The Substance as the Subject of a Health Claim

IDFA agrees with FDA's assessment that health claims should not be solely based on substances found in food but rather inform consumers what foods can provide a beneficial substance. IDFA strongly believes that consumers statements that expressly include the food name such as "Yogurt can help reduce the risk of osteoporosis" are more useful to the consumer that statements that only reference the substance

"calcium can help reduce the risk of osteoporosis." Since industry is better able than FDA to determine how best to communicate with consumers regarding the health benefits of its products we request that both options referring to either a substance or a food containing a specific substances that be allowed.

IDFA appreciates the opportunity to furnish comment in response to the FDA's advance notice of proposed rulemaking (ANPR) addressing health claims and dietary guidance for conventional food and dietary supplements. We would welcome the opportunity to discuss these issues, and would be happy are also glad to answer questions or provide additional information.

Respectfully submitted,

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