



September 7, 2004

Division of Dockets Management
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Docket Nos. 1994P-0390 and 1995-0241

To Whom It May Concern:

The International Dairy Foods Association (IDFA) appreciates the opportunity to provide comments to FDA regarding health claims and nutrient content claims. We recognize the importance of these claims to consumers who are concerned about their health.

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.

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. Our comments are organized in response to each of issues laid out by FDA in the May 4, 2004 Federal Register notice.

IDFA supports regulations that will give the food industry the greatest amount of flexibility in providing accurate health and nutrition information to consumers. This will enable consumers to make the best food decisions, based on their health requirements.

The Minimum Nutrient Contribution Requirement

IDFA supports the current FDA policy of requiring a minimum content of certain nutrients, with allowance for exceptions to be made for specific foods. The minimum nutrient contribution should continue to be based on naturally occurring nutrients, not on high levels of fortification found in some foods. Foods making health claims should provide a positive contribution to a consumer's overall diet.

The nutrient density approach should not be used as a basis for determining eligibility for health claims because nutrient density is not yet widely accepted in the general nutrition community nor has consensus been reached on a definition of nutrient dense foods. According to the nutrient density proposal, the percent Daily Value for calories should not be higher than the percent Daily Value for certain nutrients, such as vitamin A, vitamin C, calcium, iron, protein and fiber. If a product contains 7% of a person's daily calories, but provides 6% of the Daily Value each of calcium, vitamin A and protein, this food could arguably be part of a healthy diet and should be allowed to make an appropriate health claim. However, under the nutrient density proposal this food would not be allowed to make any health claim.

Disclosure versus Disqualifying Nutrient Levels for Health Claims

IDFA supports disclosure of nutrient levels when making health claims, rather than disqualifying foods from making claims. Instead of disallowing a food from making health claims based on whether or not that food contains higher levels of certain nutrients, such a food could still provide a positive health benefit and should be eligible for health claims. Certainly if the nutrient that is at a higher level has a direct impact on the disease referenced in the health claim, this should not be allowed. However, for foods that are good or excellent sources of a nutrient that would impact one disease but have levels of nutrients that would currently disqualify them from making a health claim, disclosure should be used to inform consumers. For instance, whole milk is an excellent source of calcium, which helps prevent osteoporosis, but is currently prevented from making an osteoporosis health claim by its level of saturated fat. A disclosure statement about the level of saturated fat would inform consumers in case they were concerned about their fat intake. However, consumers who are not concerned about their fat intake, but are concerned about preventing osteoporosis would be able to learn that whole milk may help in their prevention efforts.

Use of "May" in Health Claims

IDFA would support the elimination of the requirement to use "may" in health claims because the use of the word "may" leads to uncertainty about the science behind the claim. While it was originally required in health claims in order to communicate the idea that diet is one of many factors contributing to the development or prevention of disease, "may" can be misunderstood. As noted by FDA in an earlier Federal Register notice, 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."

With the beginning of qualified health claims, FDA has the opportunity to require additional information to make statements clear to consumers and an accurate reflection of the science. The health claims that have met significant scientific agreement are backed by proven science and do not need the qualifiers currently required by FDA regulation. For each of these claims, the link between the food or component and the disease has been proven and qualifiers, such as "may" that suggest doubt, should not be required.

IDFA strongly supports the proposal to remove the qualifier "may" from unqualified health claims so that the uncertainty surrounding claims containing the word "may" is eliminated. An example of a health claim without the qualifying "may" is: "Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and reduce their high risk of osteoporosis later in life." In addition to removing "may" from unqualified claims, such as this model claim, we also believe that other information can be removed to simplify the claim. This is detailed further in our comments about abbreviated health claims.

Synonyms in Nutrient Content Claims

Additional terms that consumers understand would provide additional flexibility and understanding for consumers and dairy processors. IDFA members would support the use of appropriate synonyms in nutrient content claims.

While there are many synonyms that could be used to make nutrient content claims, there are also many that could be too ambiguous for consumers. The "anchoring" concept will allow useful synonyms to be used, without confusing consumers with unclear terminology. One example of a claim that is understood by consumers and should be allowed through the anchoring concept is "nonfat" as a synonym to "fat free." However, terms should be proven to be understandable before they are used. Statements such as "Great source of ---" may not allow consumers to differentiate between a "Good source" level or an "Excellent source" level.

Abbreviated Health Claims

IDFA would strongly support the allowance of abbreviated health claims on food labels. An abbreviated health claim that references the entire health claim elsewhere would be a great benefit to consumers and food manufacturers. Products that previously qualified for health claims but could not make them because of a lack of space on the label would be allowed to make the health claims for which they qualify. Although the claim will not be all together, the information is still all available and easily accessible to a consumer at the point of purchase.

Since health claims require so much space and many dairy food labels are relatively small, dairy processors have been utilizing structure/function claims instead of health claims. In order to give consumers information regarding the link between dairy, calcium and bone health, structure/function claims, such as "The calcium in milk helps build stronger bones" have been used instead of the osteoporosis health claim. While the structure/function claim provides helpful information to consumers, an abbreviated health claim would provide additional flexibility and allow statements regarding osteoporosis. This would give consumers even more health information by presenting the information in another format.

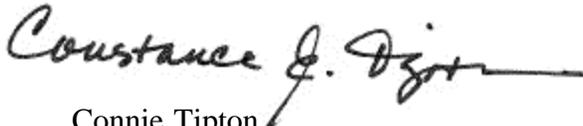
Additionally, IDFA believes that the reference to populations of "white and Asian women" in the osteoporosis health claim is unnecessary since many populations, including a variety of races and genders, with low calcium intake are at potential risk for osteoporosis. An example of a claim without such a reference would read: "Regular

exercise and a healthy diet with enough calcium helps teens and young adults maintain good bone health and reduce their risk of osteoporosis later in life."

Although the osteoporosis and calcium health claim has a proposed abbreviated claim, this claim was never finalized for use on food labels. In addition to the osteoporosis claim, dairy foods' strong nutrient profile also makes them eligible to use other health claims. Many dairy foods do not have the label space to print the entire claim all together and so do not make these claims. Unfortunately, this means that consumers are often unaware of the health benefits of dairy beyond prevention of osteoporosis. The ability of dairy foods with small labels to provide an abbreviated health claim with the entire claim elsewhere would alert consumers to more of dairy's health benefits and could attract new consumers to a healthy product because of a specific health claim.

In summary, IDFA believes that the process for using health claims and nutrient content claims should be as flexible and easy as possible for qualified foods, but should also maintain consumer confidence in such claims. 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. The dairy industry looks forward to providing consumers healthy products labeled with accurate and effective health information.

Regards,

A handwritten signature in cursive script that reads "Connie Tipton". The signature is written in black ink and is positioned above the printed name and title.

Connie Tipton
President and CEO