



NATIONAL DAIRY COUNCIL®

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Division of Dockets Management
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Docket Nos. 1994P-0390 and 1995P-0241. Food Labeling: Nutrient Content Claims, General Principles; Health claims, General Requirements and Other Specific Requirements for Individual health Claims; Reopening of the Comment Period

Dear Sir or Madam:

The NATIONAL DAIRY COUNCIL® (NDC) submits the following comments on the docket referenced above.

NDC is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. The NATIONAL DAIRY COUNCIL® has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NATIONAL DAIRY COUNCIL® is recognized throughout the nation as a leader in nutrition research and education.

Regulations authorizing health claims have now been in place for over 10 years. Unfortunately many of the authorized health claims are not being used in the marketplace. Reasons for lack of use are many, including 1) messages are too lengthy; 2) messages are not compelling to consumers; 3) other regulatory restrictions (minimum nutrient requirements, disqualifying levels, etc.) prohibit using a health claim on some foods.

FDA recognized some of these issues and in December of 2002 announced the Consumer Health Information for Better Nutrition Initiative (CHIBNI). CHIBNI was designed to improve the “public availability and consumer understanding of up-to-date scientific evidence on how dietary choices can affect health.” A key tenet of CHIBNI is that “a better-informed public, supported by effective, science-based regulation of health information, would be expected to make better nutritional choices.” FDA indicated the desire to “encourage food and dietary supplement producers to compete in ways that better protect the public from disease risks.”

NDC appreciates the opportunity to provide comments on the topics solicited by FDA in the reopening of the comment period [69 FR 24541] related to the agency’s 1995 proposed rule entitled “Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General

Requirements and Other Specific Requirements for Individual Health Claims [60 FR 66206] (the 1995 proposal). Specifically, NDC wishes to comment on: 1. the minimum nutrient contribution requirement, 2. disqualifying nutrient levels, 3. Specific requirements for health claims and use of the word “may” in unqualified health claims to describe the relationship between a substance and a disease or health-related condition.

I. Minimum Nutrient Contribution Requirements

In light of the FDA task force report’s recommendation, FDA is requesting comments on the proposed amendments to Sec. 101.14(e)(6) in the 1995 proposal [1]. The matter is whether and how FDA could provide additional flexibility with respect to the 10 percent nutrient contribution requirement for foods bearing a health claim.

The task force is specifically seeking comments on the use of a nutrient density approach as an alternative to the current 10 percent nutrient contribution requirement, including scientific support or other rationale on how the approach will or will not ensure that foods with little or no nutritional value do not bear health claims.

- A. FDA’s concerns about preventing misleading health claims are well founded and the agency’s logic and principles for establishing minimum nutrient contribution requirements for health claims are sound.** Conventional foods bearing such claims should make a significant nutritional contribution to the diet and be consistent with the Dietary Guidelines for Americans.

- B. NDC believes science will benefit from further review of nutrient density as a concept for establishing minimum nutrient contributions to increase the number of healthy foods eligible to bear health claims**

The basic concept of nutrient density is part of the foundation of established and emerging dietary guidance, and further review of nutrient density is a valid approach to establishing minimum nutrient contribution requirements. Nutrient density can help identify healthy foods that contribute multiple nutrients to the diet, though they may not all be present at 10 percent Daily Value. As obesity rates rise and more focus is placed on moderating caloric intake to match energy expenditure, the concept of nutrient density can be a valuable complement to help the public understand the importance of consuming foods containing more nutrients and fewer calories. With this approach, consumers can be encouraged to eat nutrient dense foods first, and then consume less nutrient-dense foods if their daily calorie intake and physical activity levels allow.

Available scientific research supports the need for more work to be carried out to determine the best way to define and implement the nutrient density concept. There are well-established efforts among the research community to use nutrient density on a population basis, as seen in a 2004 IOM report [2]. There is also a strong interest among the scientific community in developing approaches to apply the concept on an individual food basis, as illustrated by data presented at a symposium recently held on naturally nutrient dense foods in Washington DC [3]. The FDA will benefit by monitoring research efforts underway to apply the concept of nutrient density in dietary guidance. These efforts could provide valuable information and recommendations for future outreach and help establish criteria to ensure that foods with little or no nutritional value do not bear health claims.

C. Appropriate criteria can prevent indiscriminate fortification of the food supply to qualify for health claims

Fortified foods present challenges for establishing criteria for making health claims. An approach with sound scientific and nutritional principals behind it is that conventional foods, which have been identified as appropriate vehicles for fortification and provide nutrients established as low or lacking in the food supply should be allowed to make a health claim based on those fortified nutrients. Examples include folic acid in cereals and vitamin D in milk [4]. Under the same approach, foods fortified solely for the purpose of making a health claim would not be allowed to make one.

If a nutrient density approach is implemented, it is possible that food processors would fortify low-energy and low-nutrient dense foods to meet the standards of a health claim. Using calcium as an example, many food manufacturers are fortifying their products with high levels of calcium as well as myriad other nutrients to gain a market advantage without considering the full impact on the population as a whole. An increasingly large number of foods are being fortified with calcium – many at relatively high levels. This has raised concerns by experts that indiscriminate fortification of foods with high levels of calcium may increase the chance that population subgroups who are not at risk for calcium inadequacy will consume unacceptably high levels of calcium above the Tolerable Upper Intake of 2500 mg/d. Furthermore, many calcium fortified foods in the marketplace are currently out of compliance with the 1980 FDA food fortification policy (21 CFR §104.20):

- Many foods are fortified with calcium at levels much higher than 50 mg/100 kcals recommended by FDA (many > 300 mg/serving).
- Foods with low nutrient density, such as candy, water, juice drinks and snack foods are being fortified with calcium.
- Foods fortified with high levels of calcium are target marketed to subgroups of the population that are at low risk of calcium inadequacy and who are most vulnerable to over consumption based on dietary patterns.
- Currently, it is not possible to evaluate the extent of calcium or other nutrient over consumption in the U.S. population because national nutrition surveys do not provide quantitative information about nutrients consumed from dietary supplements and fortified foods.

As opposed to foods that make a significant contribution to the food supply, foods fortified solely for the purpose of making a health claim by definition are considered supplements. These fortified foods fit differently within dietary guidelines and may lead to consumer confusion if allowed to make a health claim based on fortified nutrient content. Such fortified foods and beverages are unlikely to provide nutrient value of significance in building a healthy diet.

A nutrition focused policy will likely require exceptions to the application of nutrient density when it would limit foods identified by the Dietary Guidelines Advisory Committee as selected food groups that should be consumed to improve public health, namely fruits, vegetables, whole grains and low fat and fat-free milk and milk products [5]. The impact of these food groups on public health outcomes has been clearly illustrated in the Dietary Approaches to Stop Hypertension (DASH) study [6]. As the

DASH study indicated, a variety of nutrients, aside from vitamins A and C, iron, calcium, protein and fiber, play an important role in public health. Therefore, the list of nutrients required to be present at 10 percent Daily Value could be expanded to reflect the latest data from dietary surveys and dietary recommendations, such as, folate, potassium, phosphorus, thiamin, riboflavin, niacin, and vitamins B6 and B12 [7]. In addition, it is important to note that aside from contributing commonly acknowledged nutrients, such as, potassium, magnesium, fiber and calcium, these foods also provide bioactive compounds and phytochemicals, not otherwise accounted for on the label. All forms of these foods should be permitted if they also meet the other requirements including the disqualifying levels as discussed elsewhere in these comments.

II. Disclosure versus Disqualifying Nutrient Levels for Health Claims

A. Use of disclosure nutrient levels, rather than disqualifying nutrient levels, may be helpful in encouraging the use of health claims

NDC believes consumers would be better informed if more health claims were used on food packages. One way to foster more utilization of currently authorized health claims is to convert disqualifying levels to disclosure levels. Many health professional organizations believe that all foods can fit in a diet. In many ways the disqualifying nutrient levels foster a “good food, bad food” paradigm that is inconsistent with almost all dietary recommendations promulgated by both government and health professional organizations. Converting disqualifying levels to disclosure levels is one action FDA can take that might increase the number of health claim messages being used by the food industry.

B. Disclosure nutrient levels are scientifically appropriate for nutrients unrelated to the health condition of interest (e.g., sodium levels are unrelated to osteoporosis risk)

An important implication of the CHIBNI is to allow more truthful and non-misleading statements about the role foods and dietary practices can have on health. One area that may foster more competition in providing health information to consumers is to revise the current regulations regarding disqualifying nutrient levels for health claims. NDC notes the original comments of the National Food Processor Association that under certain instances disqualifying levels should be eliminated and/or replaced with disclosure levels. For example, we believe if FDA allowed communication of the relationship of calcium to osteoporosis risk reduction on calcium-rich dairy products which exceed the disqualifying level for sodium (a nutrient that is virtually unrelated to osteoporosis risk), many food manufacturers would seriously consider using this health claim. We do not believe this would be misleading to consumers and we believe this would be consistent with NLEA in that it would aid consumers in constructing total daily diets that meet the Dietary Guidelines for Americans. In this particular example consumers would be encouraged to increase consumption of dairy products (Americans only average 1.5 servings of dairy per day and the majority of the population is not obtaining the recommended level of calcium in the diet [8]) while at the same time being overtly informed of the sodium content of any products that exceed 480 mg/serving.

C. Scientifically based criteria would be needed to convert disqualifying nutrient levels to disclosure nutrient levels

If FDA is still concerned that allowing foods that exceed the disqualifying levels would not aid consumers in constructing total daily diets that meet the Dietary Guidelines for Americans, the agency could establish scientifically based criteria allowing foods that exceed the disqualifying level to convey certain health messages. For example, FDA could allow disqualifying levels to be converted to disclosure levels if the food manufacturer has scientific data supporting that the food in question does not increase the risk of the health related conditions associated with the four disqualifying nutrients. For example, if a high calcium food that exceeds the saturated fat disqualifying level can show that reasonable incorporation (based on dietary survey consumption data) does not raise blood LDL-cholesterol levels, then this product would be allowed to convey calcium related health messages, with a disclosure statement to “See nutrition information for saturated fat content.”

From a nutritional standpoint, an informed public is essential if Americans are going to improve their health through changes in dietary practices. Allowing more products to communicate health claims, even if they include disclosure statements, is consistent with CHIBNI and the broader FDA mandate to assist the public in making wise dietary choices that benefit long-term health.

III. Specific Requirements for Health Claims and use of the word “may”.

A. The Calcium and Osteoporosis Health Claim

FDA’s proposed modification of the Calcium and Osteoporosis Health claim that limits the claim to teen and young adult women rather than to the general population is inconsistent with the current science.

1. Background:

In the 1995 proposal [9], FDA recognized that osteoporosis affects more than 25 million people in the U.S. and is the major cause of bone fractures in postmenopausal women and the elderly (men and women). Furthermore, FDA acknowledged that the use of health claims on food products is not great, in part because of their lengthy wording and onerous language, and that too many words detract from the central consumer message of the claim. FDA also noted that consumer research conducted by the agency identified the calcium and osteoporosis health claim as the one most actively disliked because of consumer misunderstanding of the populations at risk for the disease due to allowing the claim to reference only white and Asian women. An example model claim:

“Regular exercise and a healthy diet with enough calcium help teens and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life”

FDA points out that given the tremendous cost of osteoporosis to public health, it is essential that the Calcium and Osteoporosis health claim inform consumers, particularly those at great risk for the disease, of the importance of adequate calcium intake throughout the life cycle. Accordingly, in the 1995 proposal [9], FDA proposed to simplify and streamline the requirements for a Calcium and Osteoporosis

Health Claim by proposing to retain the requirement that the claim NOT suggest that the risk of osteoporosis applies equally to the general U.S. population. However, it proposed to remove the required reference to any racial or ethnic group as the at-risk population. In its place, however, FDA proposed:

“The claim shall identify the population at particular risk for the development of osteoporosis as women in their bone forming years from approximately 11 to 35 years of age”.

FDA pointed out that the scientific basis for retention of teen and young adult women, irrespective of race or ethnicity, as the focus of the claim is underpinned in a statement from the 1994 “NIH Consensus Statement, Optimal Calcium Intake” [10]:

“Two important factors that influence the occurrence of osteoporosis are optimal bone mass attained in the first two or three decades of life and the rate at which bone is lost in later years.”

FDA’s proposed Model Health Claims for Calcium and Osteoporosis:

“Especially for teen and young adult women, adequate calcium in a healthful diet may reduce the risk of osteoporosis later in life.” Or

“A healthful diet with adequate calcium and regular exercise help teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.”

Current scientific consensus on calcium and osteoporosis, and its public health implications, argues strongly for revising the Calcium and Osteoporosis Health claim to focus on both males and females at all life stages.

2. Scientific support for a general population based Calcium and Osteoporosis health claim.
 - a. The risk of osteoporosis affects more Americans than just teen and young adult women.

Osteoporosis is a major public health threat for an estimated 44 million American men and women, or 55 percent of the people over 50 years of age and older. Ten million adult and adolescent males and females already have the disease and almost 34 million more are estimated to have low bone mass, placing them at increased risk for osteoporosis [11]. Of the 10 million Americans estimated to have osteoporosis, 8 million are women and 2 million are men. One in two women and one in four men over age 50 will have an osteoporosis-related fracture in her/his remaining lifetime.

Men and osteoporosis – Clearly, the predominant sector of the population affected by osteoporosis are women, as 80 percent of those affected are women. However, the problem of osteoporosis and its public health implication are under appreciated in men. Fully 20 per cent of those affected are men. It is estimated that one-fifth to one-third of all hip fractures occur in men and that after age 50, 6 percent of all men will suffer a hip fracture as a result of osteoporosis [12]. Osteoporosis develops less often in men than in women. However, in the last few years the problem of osteoporosis in men has been recognized as an important public health issue, particularly in light of

estimates that the number of men above the age of 70 will double between 1993 and 2050 [12]. The estimated national direct expenditures (hospitals and nursing homes) for osteoporotic and associated fractures was 17 billion in 2001 (\$47 million each day) and the cost is rising [12]. Hence, it is clear that the risk of osteoporosis as a public health issue and the associated health care costs cuts across both genders as well as all life stages.

- b. Following are selected comments and conclusions from the NIH Consensus Statement 2000: Osteoporosis Prevention, Diagnosis, and Therapy. March 27-29, 2000 [13].
- Osteoporosis occurs in all populations and at all ages. Though more prevalent in white postmenopausal females, it often goes unrecognized in other populations.
 - Adequate calcium and vitamin D intake are crucial to develop optimal peak bone mass and to preserve bone mass throughout life.
 - Calcium is the specific nutrient most important for attaining peak bone mass and for preventing and treating osteoporosis.
 - The Institute of Medicine recommends calcium intakes of 800 mg/day for children ages 3-8 and 1,300 mg/day for children and adolescents ages 9-17. However, only 25 percent of boys and 10 percent of girls ages 9-17 are estimated to meet these recommendations.
 - Factors contributing to low calcium intakes are restriction of dairy products, a generally low level of fruit and vegetable consumption, and a high intake of low calcium beverages such as sodas.
 - For older adults, calcium intake should be maintained at 1,000 to 1,500 mg/day, yet only about 50 to 60 percent of this population meets this recommendation.
 - Regular exercise, especially resistance and high-impact activities, contributes to development of high peak bone mass and may reduce the risk of falls in older individuals.

Taken together, these recent conclusions and recommendations about the prevalence, risk and prevention of osteoporosis for Americans highlight that, although the predominant sector of the U.S. population affected by osteoporosis are women, the risk of osteoporosis also affects a significant number of men and all age segments of the population. Importantly, many of the scientific documents on risks and prevention strategies for osteoporosis cited herein emphasize all population groups [11-13], not just teen and young adult women as a high priority for risk prevention than other population groups.

Hence, the scientific rationale to identify only teen and young adult women from approximately 11 to 35 years of age as the focus for the revised Calcium and Osteoporosis health claim as proposed in FDA's 1995 proposal [9] is not consistent with current scientific and health professional conclusions and recommendations.

The claim language proposed by FDA: *“Especially for teen and young adult women, adequate calcium in a healthful diet may reduce the risk of osteoporosis later in life,* [9], ignores significant sectors of the U.S. population who may be at particular risk for osteoporosis especially men and older Americans.

It may be in the best interests of U.S. consumers for FDA to re-evaluate its position and recommendations for a revision to the Calcium and Osteoporosis health claim

based on the more recent scientific conclusions and recommendations. A Calcium and Osteoporosis health claim for the general population would be highly consistent with current scientific conclusions and recommendations [11-13].

Examples of such a claim would be:

“Getting enough calcium along with a healthful diet may reduce the risk of osteoporosis”

“Eating a healthful diet with adequate calcium can help reduce the risk of osteoporosis”

This approach acknowledges FDA’s concern that the claim not imply that adequate dietary calcium is the only recognized risk factor for a reduced risk of osteoporosis. The second example provided replaces the word “may” with “can help” as an approach that indicates to consumers that osteoporosis is a multifactorial disease. Furthermore, this approach has the potential to reduce the concern that consumers interpret the word “may” as a reflection of a lack of scientific support for the claim. Certainly there are other examples that could be developed that would be consistent the science, understandable by consumers, and manageable for use on food labels.

FDA should be commended for undertaking steps to help increase the utilization of health claims on food labels and to improve their understanding by consumers. To this end, there is clearly a need to develop a Calcium and Osteoporosis health claim that is consistent with the science, truthful and non-misleading, and equitable to all Americans.

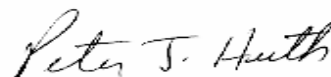
For more than 85 years, the National Dairy Council has worked to advance the state of scientific knowledge on the role and value of dairy foods in promoting and enhancing human nutrition and health. We look forward to playing an active role in the public process, and to assisting FDA in any way possible to achieve results that will benefit the health and well-being of all Americans.

Thank you for the opportunity to comment on these important issues.

Sincerely,



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