



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

**Re: 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; 69 Fed. Reg. (May 4, 2004)**

The Grocery Manufacturers of America (GMA)<sup>1</sup> appreciates this opportunity to offer comments concerning the Food and Drug Administration's (FDA) reopening of the comment period on general principles regarding nutrient content claims and health claims in food labeling.

## **Background**

Given the time that has elapsed since the original 1995 proposal, GMA took the opportunity to review past comments that GMA submitted to the agency on the General Principles for Nutrient Content Claims and Health Claims. GMA's positions taken a decade ago are still relevant today. GMA intends to analyze the issues within the framework of FDA's own goals. A number of FDA officials, at various levels of the agency including that of the Commissioner's office, have recently articulated three overriding goals that the agency has had in drafting its food labeling proposals: (1) to clear up confusion in the marketplace; (2) to inform consumers and assist them in making food choices; and (3) to provide incentives to the food industry to produce innovative, healthful products. In a November 1991 Congressional hearing, then Commissioner Kessler stated that the new food label should give companies that manufacture healthier foods the tools to tell consumers about those products additionally, in remarks presented at a GMA meeting, then Deputy Commissioner Taylor affirmed the agency's belief that the free flow of truthful

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<sup>1</sup> GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers and sales agencies at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

information on food labels is properly considered a good thing – that it is essential to our free market economy and plays an important role in informing consumers. GMA fully supports the agency’s goals, which, if achieved, would appear to serve well the interests of the American public, the FDA and industry. We also strongly agree with FDA’s recognition of the positive role of nutrition information in helping consumers make food choices.

The agency stated very early on that the NLEA provision on health-related claims “reflects a determination by Congress that an orderly and accountable process is needed to control the dissemination of information [on diet/disease relationships]...on the food label and in labeling” [60537, emphasis added]. In fact, the primary Congressional purpose for the provision is to facilitate such claims, which “can reinforce the Surgeon General[‘s] recommendations and help Americans to maintain a balanced and healthful diet” [H.R. Rep. No. 101-538, 101<sup>st</sup> Cong., 2<sup>nd</sup> Sess. (1990); “Nutrition Labeling and Education Act of 1990”]. To emphasize that the agency’s mandate is to “control” rather than “facilitate” health-related claims suggests that regulations should be written so as to limit as far as possible the dissemination on food labels of the kind of information the Surgeon General and other health authorities want the public to receive. This is the wrong emphasis. It does not reflect the intention of Congress, and will not further FDA’s goals of informing consumers and stimulating food product innovation”. It also violates the 1<sup>st</sup> Amendment, which favors disclosure over suppression.

GMA has taken the position, which we still espouse, that FDA has always had the authority to permit truthful, adequately supported and adequately qualified disease-related information to appear on food labels and labeling. GMA further believes that FDA regulations and policies should avoid any age-related restrictions for nutrient content claims and/or health claims for infants and/or young children. As long as they are scientifically supported, nutrition and health claims for infants/young children should be encouraged, in order to improve the diet of the population during these formative years. Parents need information about the nutrient content and health effects of the foods they are choosing for their infants and/or young children.

#### **A. Section 101.14 (e)(6): The Minimum Nutrient Contribution Requirement**

GMA believes this regulation also prohibits health claims for other important food products where they would be appropriate. GMA urges that the unintended consequences of this regulation be reduced. One way suggested by GMA members would be by expanding the list of six permitted nutrients (vitamin A, vitamin C, calcium, iron, protein, or fiber) per reference amount customarily consumed (RACC) to include any nutrient for which the National Academy of Sciences has established an RDI, to permit greater flexibility in demonstrating nutritional contribution. GMA believes there is no justifiable scientific basis for limiting the nutrient contribution of a food to these six nutrients. Many foods have 10 percent of the RDI for important nutrients that are not on the list of 6 established in Section 101.14(e)(6).

Some foods have a broad distribution of nutrients, but not a high level of any particular one (e.g., a combination of two or more nutrients that have DRIs, each at levels of at least 2 percent of the RDI/RDA, representing a combined total of at least 10 percent of the RDIs/RDAs, but not 10

percent for any particular one). This approach would permit such claims where they are justified.

Other foods that are currently prohibited from making a health claim are fortified foods, including those fortified in accordance with FDA food standards, in order to achieve important public health purposes. It is particularly important to permit health claims based on appropriate fortification. Otherwise, there would be no incentive for the food industry to add important nutrients to their products to improve nutritional quality. FDA should not promulgate a regulation that directly discourages appropriate food fortification. Prohibition of claims based on fortification would be inconsistent with FDA's longstanding position, stated in Section 101.9(k)(6) of the final regulations, that natural nutrients are not superior to an added or synthetic nutrient unless proven otherwise by scientific evidence or consensus.

GMA also suggests amending minimum nutrient contribution requirements should be amended to permit health claims on foods that contain at least five percent of one of the nutrients, occurring either naturally or through fortification, outlined in Section 101.3(e)(4)(ii). GMA recommends this approach as an alternative to current regulation as it satisfies the Agency's desire to impose a minimum nutrient contribution requirement. In finalizing current labeling regulations, FDA recognized the significant contribution of foods containing five percent or more of the RDI. The Agency stated that daily requirements could be met when as many as 20 foods containing at least five percent of the RDA are consumed per day (58 FR, 2142, January 6, 1993).

GMA recognizes that adoption of a five percent minimum requirement would require an adjustment to current rounding regulations for the expression of vitamin/mineral content as outlined in Section 101.9(c)(8)(iii). However, this approach is harmonious with the Canadian labeling regulation, which identifies a minimum level of five percent to qualify for any vitamin or mineral nutrient claim.

In all three of the above circumstances, health claims are entirely appropriate. These parameters would ensure that health claims were made only on foods that are consistent with dietary guidelines. GMA urges the Agency to consider our recommendations as an alternative to current regulation and to the current piecemeal exemption approach by the Agency as it satisfies the Agency's desire to impose a minimum nutrient contribution requirement. GMA fully supports the use of health claims for fruit and vegetable products, and enriched grain products and bread. Health claims are entirely appropriate for these and other foods.

GMA recognizes the contribution of processed fruits and vegetables and enriched grain products to healthful diets, and supports the intent of the petitions requesting exemption from nutrient contribution requirements. The 2005 Dietary Guidelines encourages Americans to consume more fruits and vegetables and enriched grain products. However, GMA believes that the exemption approach is both discriminatory and piecemeal, and that a new regulation as outlined above provides a rational and consistent approach that should be promulgated. However, if FDA continues with this approach GMA strongly urges FDA to accept petitions to extend the exemption to other foods, and review the petitions in an efficient and timely manner.

FDA further asked for comments on fruit and vegetable products with added oils, sodium, sauces, syrups, or other ingredients. GMA believes it is important to recognize that many people are more likely to choose to eat some foods that are made more palatable with the addition of nominal amounts of fat, salt or sugar. Therefore, instead of penalizing these products, it would be more sensible to recognize that foods with “additional fat”, sodium and “added sugar” may be necessary to deliver essential nutrients and can do so without exceeding dietary recommendations.

## **B. Disclosure Versus Disqualifying Nutrient Levels for Health Claims**

Section 403(r)(3)(A)(ii) of the FD&C Act provides two separate and distinct rules relating to health claims. First, FDA may establish distinct rules relating to health claims. Second, FDA may permit claims that would otherwise fall within the disqualifying-nutrient information levels and instead require disclosure that nutrition information relating to the disqualifying nutrient may be found on a specific part of the label if FDA finds that such a claim will assist consumers in maintaining healthy dietary practices. Unfortunately, FDA has focused on the first rule and has failed adequately to consider the second rule.

FDA correctly identifies the statutory language limiting health-related claims to foods that do not contain a nutrient in an amount that increases the risk of diet-related disease, and notes that nothing in the statute or legislative history indicates “what Congress considered to be an amount of a nutrient in a specific food that would increase the risk of a disease” [60543]. We also agree with the agency’s observations that:

Although there are recommended levels for dietary intake for total fat, saturated fat, cholesterol and sodium, there are no generally recognized levels at which these nutrients in an individual food pose an increased risk of disease. Thus, FDA knows of no established or accepted approach for identifying disqualifying levels for these nutrients [60543].

GMA submits that this conclusion must end the analysis. Section 403(r)(2)(B)(ii) of the NLEA requires FDA to consider whether “the [individual] food [for which the claim is made] ... contains a nutrient at a level which increases to persons in the general population the risk of a [diet-related] disease..., taking into account the significance of the food in the total daily diet” [emphasis added]. Having concluded that individual foods do not contain nutrients that increase disease risk, even when the amount of the food normally consumed in a daily diet is considered, the agency must conclude that, at this time, it is not possible to identify any amounts of any nutrients in any specific foods that meet the statutory requirement of increasing the risk of a disease.

Single foods, even when their significance “in the total daily diet” is considered, do not increase disease risk – only total diets consisting of many foods consumed over time have that potential. The agency’s rationale for arriving at disqualifying levels of fat, saturated fat, sodium and cholesterol is flawed; it does not follow the mandate of the NLEA. As the agency states, its approach “is based upon the recommended levels for dietary intake...because deviation from the recommended levels has not been associated with an increased risk of disease” [60543]. The

NLEA, however, expressly requires consideration of the amount of the nutrient in the individual food for which the claim is being made, not generalized dietary intake of the nutrient from all food sources over time.

GMA strongly opposes the creation of “disqualifying” levels of nutrients. Instead, if FDA believes that there is a need to limit the way disease-related claims are made for foods containing certain levels of nutrients recommended by health authorities to be controlled in the diet, then the agency must implement disclosure of information about the other nutrient(s) currently provided in 21 C.F.R. § 101.14(a). The statement should be the same as the “disclosure” statement to be used in conjunction with nutrient descriptors in the same circumstance. As GMA has commented previously, the principles established in the *Pearson v. Shalala* and *Whitaker v. Thompson* decisions make clear that FDA regulations relating to disqualifying criteria of this type violate First Amendment commercial speech protection.

When the disqualifying nutrient is unrelated to the specific health claim involved, the health claim should be allowed without any disclosure requirements. Should FDA find this unacceptable, then GMA recommends that when the disqualifying nutrient is unrelated to the specific health claim involved the health claims should be allowed, conditioned upon the reference to the information available on the disqualifying nutrient.

As FDA itself has often noted, foods cannot neatly be compartmentalized into “good” and “bad” products. There is no perfect food, and many foods have both more desirable and less desirable nutrient properties. Those with disqualifying nutrient levels should not be unduly penalized. By preventing useful health claims, FDA is hindering rather than helping nutrition education in our country.

GMA recommends that FDA eliminate total fat as a disqualifier or disclosure for any health claim based on current scientific evidence<sup>2</sup>. Total fat is not related to chronic disease risk, rather the type of fatty acid is related to coronary heart disease, i.e., saturated, *trans*, monounsaturated or polyunsaturated fatty acid. GMA recommends that FDA eliminate low fat as a qualifier for relevant health claims for the same reason.

One example of the inappropriate limitations of this rule is for peanut butter. Peanut butter is prohibited from making the nut qualified health claim because of the saturated fat content. FDA waived the disqualifying level for total fat for nut products replacing it with disclosure of the total fat content. The RACC serving size for peanut butter is 2T, and therefore falls under the 50 gram rule. Peanut butter on a 30 gram basis contains 3.5 g of saturated fat well within the 4 gram disqualifying level but exceeds this level on a 50 gram basis (5.5 g).

Another example of the inappropriate limitations of this rule is for vegetable-based juices and canned vegetables that are prohibited from making health claims because of their sodium content. Vegetable juices and canned vegetables could make several health claims including

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<sup>2</sup> Institute of Medicine, Food and Nutrition Board. 2002. Dietary Reference Intake: Macronutrient Report. National Academy Press, Washington

fruits and vegetables and cancer or some of the dietary lipid claims related to cancer or coronary heart disease. It is true manufacturers provide lower sodium versions of these products (<480 mg sodium per RACC) but they are rarely purchased by consumers.

### **C. Use of “May” in Health Claims**

GMA agrees with FDA that the word “may” leads to uncertainty about the science behind the claim, since consumers are likely to interpret its use 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.”<sup>3</sup>

As presently worded, significant scientific agreement (SSA) claims are qualified not only by use of the word “may” but also by use of the word “risk” rather than a direct reference to the harm involved. “May reduce heart disease” is roughly equivalent to “Reduces the risk of heart disease.” Using both qualifiers (“May reduce the risk of heart disease”) is both redundant and semantically incorrect. A reduction in risk does not mean, of course, that all potential harm has been eliminated. Thus, GMA supports eliminating “may” as one of the two qualifiers in all SSA health claims.

### **D. Synonyms in Nutrient Descriptor Claims**

There is no need for FDA to impose a list of specific approved synonyms. The statute does not contain any such requirement.

Under Section 403(r) of the FD&C Act, each nutrient descriptor – including every synonym for that descriptor, but not including every spelling variation – must be identified and be the subject of a regulation defining and permitting use of that specific term. Section 3(b)(1)(A)(ix) of the NLEA explicitly provides, however, that in defining any of the six nutrient descriptors, FDA may include “similar terms which are commonly understood to have the same meaning,” i.e., any synonym. This provision was included in the statute explicitly to avoid the need to have a multitude of nutrient descriptor terms and identify their synonyms. GMA specifically requests that synonyms be permitted nutrient descriptors that are synonymous with the lead nutrient descriptors. The First Amendment precludes FDA from prohibiting these truthful and not misleading terms in food labeling.

If FDA persists with an “anchoring” approach, however, GMA recommends that greater flexibility be provided. GMA’s recommendation is to anchor the unlisted term to the specific quantity of the nutrient per serving. Thus, the unlisted term “loaded with fiber” could either be anchored to a specific declaration of the amount of the fiber per serving, e.g. 6 grams per serving. This approach would produce far more useful information for the consumer than the FDA approach. Consumers are unlikely to know the FDA definition of the term “high” for each nutrient. By anchoring use of an unlisted term with specific quantitative declaration of the

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<sup>3</sup> 69 Fed. Reg. at 66043 (citing 21 C.F.R. 101.14(d)(2)(ii)).

nutrient per serving, consumers would have detailed information that would enhance nutrition information and ultimately could be of importance in maintaining healthy dietary practices.

### **E. Abbreviated Health Claims**

GMA supports the recommendations to simplify health claims and to allow the use of abbreviated claims. The food industry has decades of knowledge and experience in consumer communication. FDA should approve the basic diet/disease relationship and allow the industry to determine how best to communicate that relationship to the consuming public, as long as the claims remain truthful, accurate and nonmisleading.

Moreover, there is no evidence in the legislative history to suggest that Congress intended label claims about nutrient/disease relationships to include the kinds of detailed information mentioned in this section of the preamble. There is no mandate from Congress, nor any need from a consumer deception standpoint, to require that disease-related claims on food labels “fully reflect the scientific facts justifying the claim,” including information about “nondietary elements (e.g., the need for exercise) and relevant nutrient interactions (e.g., calcium and phosphorous levels in a food)” [60541]. No food label is large enough literally to reach the stated goal of “fully reflect[ing] the scientific facts....” Moreover, it is difficult to believe that the agency would expect consumers to meaningfully comprehend information about “nutrient interactions” via a message delivered on a food label.

The example given in the calcium and osteoporosis health claim preamble is a litany of information proposed to be included within any claim about calcium and osteoporosis demonstrating the complete impracticality of the proposed regulation. The First Amendment forbids this approach.

FDA has insisted upon “model” health claims that are lengthy, detailed, and complex, and thus poorly suited for consumer understanding and communication. This approach has impeded FDA’s goals of providing nutrition and health-related information to consumers in a consumer-friendly manner and encouraging industry to offer innovative products to the public. Few food labels could physically include this quantity of information (particularly since FDA intends to require it all to appear in one place, in uniform type size on the label), and if they did, few consumers would be motivated to read it all. The net effect of this information overload is to impede the dissemination of health-related claims, not facilitate their inclusion on food labels. Yogurt, granola bars, and energy bars are three excellent examples of products that have small labels and are limited in making health claims due to the lack of label space.

GMA disagrees strongly with FDA’s interpretation of the amount of information that needs to be included in a health-related claim to comply with section 403(r)(3)(B)(iiii). To satisfy the statute, claims must be stated (1) to accurately represent the relationship between the nutrient and the disease, (2) to accurately represent the significance of the nutrient in affecting the disease, (3) comprehensible, and (4) to permit the consumer to understand the significance of the claim in the context of a total daily diet. These communication criteria do not, as FDA asserts, require that

the claim “include all relevant information” [60550]. While the specific information needed to comply with the statutory requirements is somewhat dependent on the individual nutrient/disease relationship involved, the agency’s general proposed approach goes much farther than the statute requires. It demonstrates an overly restrictive bias that will only serve to discourage the dissemination of useful information on food labels. Food labels cannot provide “all relevant information” on this, or any other subject. The NLEA does not include such a requirement, and FDA should not attempt to impose one.

In comments submitted March 10, 1997, GMA recommended that a number of health claims be simplified beyond FDA’s proposal. These included the claims for:

- Calcium and osteoporosis,
- Fiber-containing grain products, fruits and vegetables and cancer,
- Fruits, vegetables and grains that contain fiber, particularly soluble fiber, and the risk of coronary heart disease, and
- Fruits and vegetables and cancer.

We specifically recommended that Section 101.72 permit a simplified claim for calcium/osteoporosis, without a required referral to a longer claim elsewhere on the label. This claim was included in the 1995 FDA study, and the results show that FDA indeed could further simplify the requirements for this claim without misleading or confusing consumers.

GMA’s recommendations to simplify claims in Sections 101.76, 101.77 and 101.78 also should be reconsidered in light of the results of the 1995 FDA study. As the FDA study shows, simplification will not result in consumers being misled or that they will draw incorrect conclusions about products. The Agency has already implemented the recommendation to eliminate the required mention of vitamins A and C and dietary fiber in the fruit and vegetable and cancer claim.

GMA also suggests that FDA allow abbreviated claims, using headlines or symbols as long as the full claim appears elsewhere on the label. Given the option of using split claims on food packages, industry will be more likely to include disease claims on labels. This additional information ultimately will benefit consumers. Therefore, we continue to urge FDA to consider this approach.

In summary, GMA believes that the FDA study supports recommendations to simplify health claims and to allow the use of abbreviated claims.

GMA thanks the agency for this additional opportunity to comment on this important and evolving area of the regulatory environment.

Sincerely yours,

A handwritten signature in black ink that reads "Alison Kretser". The signature is written in a cursive style with a long, sweeping underline.

Alison Kretser, MS, RD

