



GENERAL MILLS

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February 25, 2004

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

Re: Docket No. 2003N-0496
Food Health Claims and Dietary Guidance
68 Fed. Reg. 66040 (November 25, 2003)

Dear Sir or Madam:

General Mills (GMI) submits these comments in response to the advance notice of proposed rulemaking (ANPR) that the Food and Drug Administration (FDA) published to solicit comment on issues related to health claims and dietary guidance for conventional food and dietary supplements, including alternatives for regulating qualified health claims in product labeling.

GMI is a Delaware Corporation with its general offices at No. 1 General Mills Boulevard, Minneapolis, MN 55426. GMI is a major packaged-food manufacturer engaged for over 75 years in the development and production of food products including flour, ready-eat-cereals, refrigerated dough products, cake and other dessert mixes, soups, vegetables, snacks and numerous other products.

We have been committed to nutrition labeling for 30 years beginning with voluntary labeling in 1974. We currently have nutrition labeling on more than 1500 retail products. Over the years, we have added additional information and claims to our products in response to consumer interest in newer knowledge about the relationship of diet and health. General Mills firmly supports changes in food-labeling practices that will provide consumers with nutrition information more relevant to today's needs.

GMI recognizes that health claims are an important tool for communicating health messages to consumers, and therefore welcomes the opportunity to comment on alternatives for regulating qualified health claims.

We support changes to the health claim regulations that allow more flexibility while ensuring truthful and non-misleading health and nutrition information on appropriate

food product labels. Allowing appropriate health information on food labels not only gives consumers a greater opportunity to make informed food choices, but it also provides food manufacturers added incentives to develop and/or promote products with health-related attributes.

Health Claims-Regulatory Alternatives for Qualified Health Claims

GMI continues to support the current requirement that “unqualified” health claims meet the Significant Scientific Agreement (SSA) standard of evidence.

Option 1:

In response to the proposed options for “qualified” health claims, we support several aspects of Option 1: Incorporating the interim procedures into regulations under notice and comment rulemaking will allow new health claim information to be available to the public in a timelier manner. Also, we support the requirements that give the FDA the opportunity to review the claim (and the supporting data for the claim) as well as the opportunity for public comment on the proposed claim.

We have concerns regarding the proposed evidence-based ranking system, however. An evidence-based ranking system may be a useful tool for a scientific evaluation of the strength of the substance and the disease relationship for a claim. Certainly this system would be understood by health professionals, but we question whether incorporating these scientific rankings into a communication tool (with applicable qualifying language) is useful or understandable to consumers.

Specifically we are very opposed to the letter grading system or other graphic symbols indicating the ranking for qualified health claims. For example, we are concerned that if a food company puts a “C” or “D” claim on their package, consumers may confuse the letter grade with the quality of the product. Also, we believe some of the proposed language distinguishing the various claim levels may be questionable or confusing. Very careful consideration and extensive consumer testing should be given to this approach before considering it as a mechanism for communicating qualified health claims.

Finally, we believe that any qualifying language should be based on the strength of the scientific data that supports the claim as proposed, rather than the strength of the data supporting the relationship between the substance and the disease.

Option 2:

We do not believe that the suggested approach in Option 2- which would require rulemaking for each new qualified health claim- is necessary. This undermines the purpose of the qualified health claim, which should allow for the flexibility to initiate and/or revise a claim as the science evolves.

Option 3:

We believe it is appropriate for FDA to have a role in reviewing qualified health claims prior to their use in the marketplace, and therefore we do not support this option. Also,

we agree with FDA's assessment that this would be an inefficient and resource-intensive approach.

Issues Raised by the Task Force Report

Data and Research on a Substance/Disease relationship, including incentives for SSA
Developing incentives for health claim-related research would be very difficult. In 1996, the Keystone National Policy Dialogue on Food, Nutrition and Health (with representations from the FDA, FTC, USDA, State agencies, other health organizations, the food industry, consumer groups and academicians) addressed this issue at length. Although there was agreement that economic incentives could be a motivating factor to initiate more research, no mechanism could be identified that could overcome the obstacles of implementing such an approach.

One possible mechanism is to develop partnerships (with industry or other groups) for publicly-sponsored research on substance/disease relationships. For example, the continued review and identification of priority issues by the Dietary Guidelines Committee can provide direction for establishing priorities for publicly-sponsored research. Support for this research could then include matching government grants or joint projects with Universities and the food industry. While this approach does not address the issue of exclusivity, it could help build the foundation for emerging but important substance/disease relationships. For example, some government-funded research regarding the health benefits of whole grain would have moved this important public health message forward in a more timely manner.

Revised Claim Language for Unqualified Health Claims

In some instances the term "may" seems unnecessary within the qualified health claim context. For example, it seems that "May reduce the risk" and "Reduces the risk" convey the same message to a consumer. However, we agree that consumer research should be conducted to identify whether the consumer interprets "may" as a reflection of the science supporting the claim rather than the certainty about the ability of the dietary practice to affect any one consumer.

We believe that allowing more flexibility in the language of the existing unqualified health claims would be an added incentive for companies to use these claims. For instance, "Eating a healthful diet low in fat may reduce the risk of cancer" adequately communicates the substance/disease relationship and eliminates the additional required descriptor "the development of cancer may be associated with many other factors including...." Or, in the case of the calcium and osteoporosis claim, the language "...helps teen and young adult white and Asian women" is not only unnecessary, but it may actually be misleading to other population groups that do not fall into this category. For instance, does it convey the unintended message to these other population groups that they have no risk or that although they may be at risk, they will not benefit by consuming calcium-rich foods?

Interim Rules for Unqualified Health Claims

GMI supports the option authorizing unqualified health claims through interim final rules (IFR). The examples cited were all for substances that have a broad base of scientific support. Any new (proposed) unqualified health claim would also have to meet the SSA standard and thus would also have a broad base of scientific support. Therefore, the risk of approving a claim that would not be scientifically supportable under IFR seems very low.

However, the FDA should have the option of not granting an IFR if there are questions about the SSA standard not having been met.

Use of phrases such as "FDA Authorized" in Qualified and Unqualified Health Claims

If this option is approved, it should be allowed for both qualified and unqualified health claims. However, careful consideration should be given to the use of any "FDA authorized" type statements to ensure that it is helpful and not confusing or misleading to the consumer.

Consumer Education

GMI has a history of providing nutrition information on food labels (as space permits) as well as in other educational materials. Examples of this include general guidance based on the Dietary Guidelines for Americans or the Food Guide Pyramid or supporting information related to specific health claims. Recognizing that there is limited space on most food labels, it is probably unrealistic to look at the label as a place to educate consumers. Consistent with the original goals of the nutrition labeling regulations, the label is only a tool to be used in conjunction with other educational efforts. It seems most appropriate that consumer nutrition and health education should be the responsibility of the food industry and other health organizations as well as the FDA.

Evaluation of Outside Scientific Groups

GMI supports the option of allowing an evaluation by outside scientific groups to review and provide scientific consensus for a potential health claim. However, we do not believe that any one group has the expertise or the resources to review all claims, nor do we believe that these groups should be selected solely by the FDA. We agree that the Food Advisory Committee (FAC) does not have the resources, the time or necessarily the expertise in all areas to be the appropriate body to review all potential claims. Also, we do not think that the Agency for Healthcare Research and Quality (AHQR) is the appropriate group to review claims regarding health and nutrition because they lack the appropriate expertise.

Utilizing third-party experts with particular expertise in a given area can be a more efficient means of obtaining the necessary scrutiny on any proposed health claim. This approach can be more efficient than to burden one government agency with the exhaustive review across a wide spectrum of expertise that could be required to properly evaluate health claims. Of course, ultimate approval authority must remain with FDA, but industry could bear the initial burden of the preparation of the data and scientific literature. A system similar to that developed for Food Contact Substance

Notifications¹ could be utilized in this regard. Industry would prepare the petition for a health claim, with all supporting evidence properly summarized, and all conclusions properly supported. The substantiation for such a petition could be reviewed by a group of third-party experts, and presented in a format that would facilitate efficient FDA review of the information and evaluation of the proposed claim (similar to the GRAS Panel report commonly submitted with GRAS Notifications).

The incentive for industry could be something as simple as making those petitions presented to FDA in this manner the subject of an Interim Final Rule (IFR) or enforcement discretion letter. This process authorizes the use of the claim pending FDA final review, after a brief period for FDA to ensure the completeness of the petition (though not review the petition on the merits). As always, the company utilizing the claim subject to the IFR or enforcement discretion letter would bear the risk that the claim is not properly supported, and may be revised by FDA after review on the merits.

Competent and Reliable Scientific Evidence

The FTC requirement and definition of “competent and reliable scientific evidence” to substantiate a claim has proven to be an effective approach for food advertising. We believe there is no reason that this standard could not be applied to supporting qualified health claims on food labels as well. Despite the use of the different terms “competent” and “credible”, the two terms are synonymous; therefore there is no reason not to continue to use the word “credible” as designated in the Nutrition Labeling and Education Act of 1990.

Issues for Further consideration

As requested, we are not addressing the issues of disqualifying nutrients or minimum nutrient content requirements at this time, but we do believe that these are important issues and encourage FDA to reopen the comment period to address these issues soon.

Dietary Guidance

GMI has a long history of disseminating health and nutrition messages on food labels and other supporting promotional materials. Therefore, we support the continued use of dietary guidance, including messages that help consumers understand reasonable substitutions. (For example, recommending lower fat dairy products as a replacement for high fat dairy products to promote more healthful dietary practices.) We have successfully communicated dietary guidance messages, such as the Dietary Guidelines for Americans and the Food Guide Pyramid, on millions of packages and we do not

¹ FDA developed the Food Contact Substance Notification (FCN) system, with input from industry, in response to Section 309 of the Food and Drug Modernization Act of 1997, which provided for premarket notification for food contact substances. This system provided a more efficient means to gain authorization for use of food contact substances, which previously had been subject to the resource intensive food additive petition process. Compared to the previous food additive petition process, in return for review within an expedited timeframe (120 days) in the FCN system, industry bears a heavier initial burden in preparing the FCN submission, and more responsibility for reviewing and summarizing the supporting data and presenting it to FDA in a format that facilitates FDA's efficient review.

believe that trying to further define the distinction between dietary guidance and health claims will be useful, and it could serve to make the communications more difficult. As a result, it will discourage rather than encourage the food industry from disseminating health information on food labels and other supporting materials.

Regulatory Distinction between Dietary Guidance and Health Claims

GMI believes that FDA's attempt to distinguish between dietary guidance and health claims has made this issue more confusing rather than clarifying it. The example given, from the National Cancer Institute (NCI), "diets rich in fruits and vegetables may reduce the risk of some type of cancer and other chronic diseases," appears to be very much like the FDA approved health claim. The only difference between the example and the approved health claim is that the NCI statement does not require that the fruits and vegetables be a good source of Vitamin A, Vitamin C or fiber. Is there significant scientific agreement to make this statement without those qualifications? If so, why are these requirements part of the health claim?

According to this proposal, FDA states that it would refer to the term dietary guidance when the statement does not refer to the substance and the disease in the same statement, and yet the example includes both substance and disease in the same sentence. We believe it would be hard for consumers to understand the distinction between the "category" of fruits and vegetable in the dietary guidance statement example and the wording in the current health claim for fruit and vegetables, which presumably discusses the relationship of the "substances" within the fruits and vegetables to disease.

Dietary guidance should be about promoting better health, not linking disease risk to a food category. An appropriate way to distinguish dietary guidance would be to recommend consumption (or avoidance) of foods or substances to enhance or promote better health. For example, "The Food Guide Pyramid recommends eating 5-9 servings of fruits and vegetables a day for good health" or "Eat 5 (fruits and vegetables) a day for good health").

Furthermore, with respect to the example of whole grains, we do not believe this can be considered a broad category of food (and thus dietary guidance) since whole grain is a *component* in a food. For example, in the *category* of breads and cereals there are foods that qualify as whole-grain and those that do not. This is demonstrated by a typical grocery store where consumers do not search for a whole grain aisle but rather find whole grains within various food product categories. It is only through the label statements, including the health claim, that the consumer can identify which products are "whole grain". One of the incentives for companies to develop and promote whole grain products is the ability to set those products apart, from those with less whole grain, by use of the whole grain health claim.

One problem with Dietary Guidance is the lack of criteria for what foods can carry the advice. Thus particular dietary guidance on a label could convey the misleading impression that the food so labeled contains (or lacks) a significant quantity of the food or substance because it is mentioned on the label.

As in the past, dietary guidance will continue to come from the Dietary Guidelines for Americans and the Food Guide Pyramid documents. These documents give companies the opportunity and the flexibility to incorporate this advice on packages and in other educational materials without the need for "model language" or to state a disease relationship. Thus, there is no need for FDA to attempt to insert an additional regulatory layer regarding dietary guidance. So long as the statement is truthful and not misleading, it is an appropriate candidate to appear on a food label.

Substance as the subject of the Health Claim

In response to FDA's request for comment on the usefulness of statements that expressly include the substance as the basis for the claim, we believe these claims need to be evaluated on a case-by-case basis. For instance, the example given- "Yogurt may reduce the risk of osteoporosis" - may be appropriate since yogurt is a dairy based food and therefore "calcium rich". However, in the case of non-traditional sources of calcium, such as fortified orange juice or cereal, it would be important to state "Orange juice- rich in calcium- may reduce the risk of osteoporosis" since these foods are not typically considered sources of calcium.

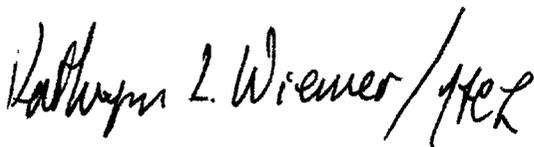
Use of Food Category Substitutions or Replacements as a Form of Dietary Guidance

It is important that substitutions and replacement statements be allowed in the context of dietary guidance. We believe further restrictions/regulations will hinder the dissemination of the publicly available information such as the Dietary Guideline for Americans or the Food Guide Pyramid messages.

Dietary Guidance on Food Labels

As stated in the comments above, it would be too limiting to have FDA or other agencies specifically define dietary guidance statements. If companies are to be encouraged to promote health messages, they need to have the flexibility to develop statements that are appropriate and compelling as long as they are truthful and not misleading.

Respectfully submitted,



Kathryn L. Wiemer, MS, RD
Senior Manager
General Mills Bell Institute of Health and Nutrition